

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

In re: SANOFI-AVENTIS SECURITIES LITIGATION

07-CV-10279 (GBD);  
08-CV-00021 (GBD)

CLASS ACTION

This document relates to:

**ECF CASE**

ALL ACTIONS

**DECLARATION OF  
MARCIA KRAMER MAYER, PH.D**

April 25, 2012

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## I. SCOPE OF ASSIGNMENT AND SUMMARY OF OPINION

1. Counsel for Sanofi (“Sanofi” or “the Company”) has asked me to opine on whether the two statements alleged by New England Carpenters Guaranteed Annuity Fund and Hawaii Annuity Trust for Operating Engineers (“Plaintiffs”) to be false and misleading meet the Second Circuit’s standards for materiality and reliance in connection with Plaintiffs’ motion for class certification:<sup>1</sup> Defendant Gerard Le Fur’s February 24, 2006 statement that “no additional trial in obesity has been requested by the FDA,” and Defendant Hanspeter Spek’s October 31, 2006 statement that “we have not submitted new data in this respect” (referring to new additional clinical trials).<sup>2</sup>

2. In my opinion, neither statement meets the requisite standard for materiality or reliance. I base this conclusion on event study evidence for Sanofi ADS on June 11, 2007. Contrary to Plaintiffs’ assertion that the relevant facts were not revealed until June 13, 2007, by June 11 the market was aware of the information Plaintiffs allege Defendants failed to disclose: “material adverse information regarding the FDA approval process and serious adverse effects associated with the use of rimonabant.”<sup>3</sup> Sanofi’s ADS price did not significantly fall on June 11 when these allegedly materially adverse facts were disclosed. This finding, robust to a wide range of market model specifications, strongly undercuts Plaintiffs’ claim that the omitted information was material. I have also conducted event studies for the ordinary shares and find the same conclusions for that security as well.

3. The June 11 event study evidence is particularly compelling because the allegedly omitted information made public that day was accompanied by other negative news, namely, the FDA’s finding of a statistically significant association between rimonabant and suicidality, and

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<sup>1</sup> Notwithstanding the fact that Defendants have stipulated to the efficiency of the market for Sanofi’s American Depository Shares (“ADS”) and do not dispute that the alleged misrepresentations were publicly made, Plaintiffs “must demonstrate materiality by a preponderance of the evidence” in order to be entitled to *Basic*’s fraud-on-the-market presumption of reliance. See *In re Moody’s Corporation Securities Litigation*, 274 F.R.D. 480, 489 (S.D.N.Y. 2011). If Plaintiffs prevail on materiality, thereby gaining the presumption of reliance, Defendants may seek to rebut that presumption.

<sup>2</sup> In its ruling on Defendants’ motion to dismiss, the Court deemed each of these statements to be an actionable misrepresentation. *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 557-58, 562 (S.D.N.Y. 2011) (“Order”).

<sup>3</sup> Lead Plaintiff New England Carpenters Guaranteed Annuity Fund and Hawaii Annuity Trust for Operating Engineers Memorandum in Support of Renewed Motion for Class Certification, February 1, 2012 (“Renewed Class Cert Motion”) at 1-2.

no positive news. That there was *not* a statistically significant price drop under these circumstances strengthens the conclusion that the market simply did not view the alleged misleading statements or omissions on February 24, 2006 or October 31, 2006 as material. Along with establishing that the omitted information was not material, the absence of a significant price drop on disclosure severs the link between the alleged misstatements and price that the presumption of class-wide reliance requires if it is to withstand rebuttal.

4. Plaintiffs falsely assert that June 13 is the corrective disclosure date. They would have the Court believe that because bad news about rimonabant's approval prospects entered the market that day and the ADS and ordinary shares sustained a large price drop, the news must have been corrective. In fact, it was not so and the accompanying price drop is therefore not relevant to this litigation. Because the alleged corrective information was already widely known to the market on June 11, 2007, its repetition on June 13 did not constitute news and therefore *could not* have moved price if, as alleged, the market were efficient. What *did* constitute news and *can* explain the ADS' statistically significant price drops on June 13 and June 14 and the ordinary shares' statistically significant price drop on June 14 are negative comments by an FDA presenter during the FDA Advisory Committee ("AdCom") meeting about the weight to be accorded the findings regarding suicidality (expressions of concern about rimonabant's safety profile based on the FDA's analysis of the data), more negative comments from AdCom members, and news of the AdCom's unanimous vote to recommend that the FDA not approve the drug at that time. None of these is alleged to have been an omitted fact necessary to have been disclosed to make the February 24 or October 31 statements not misleading. Because Defendants could not possibly have known in February or October 2006 the opinions that would first be expressed at the AdCom meeting by certain FDA staffers and AdCom panel members on June 13, 2007 and are not alleged to have known of those opinions, the June 13 price drop is a red herring, not something indicative of materiality or reliance.

5. The June 11 price evidence is determinative and therefore sufficient to support my conclusion that neither materiality nor class-wide reliance can be demonstrated in this case.

6. This conclusion is reinforced by four additional types of evidence that I found in the course of my investigation:

- **Event studies of price behavior following the challenged statements when made.** Neither statement was followed by a statistically significant rise in ADS price. Under this Court's ruling in Moody's, the lack of a significant price increase on these occasions is consistent with the absence of a link between the statements and the ADS price.
- **Analyst comments about rimonabant's health risks.** Throughout the purported class period, analyst reports noted rimonabant's potentially adverse psychiatric side effects, including depression and suicidality. The market's widespread awareness of these risks, coupled with its knowledge (gained on announcement of the approvable letter) that the FDA was unwilling to approve rimonabant without more information, may well have rendered the alleged omissions (about what particular additional information the FDA was seeking) immaterial.
- **Analyst and investment manager comments about rimonabant's uncertain approval prospects.** Five of the ten analysts who discussed rimonabant in a report issued on June 11 or June 12, 2007 noted the risk of non-approval or a less-than-unanimous Panel ratification in their last previous report on the Company. In internal emails from October 2006 into May 2007, Boston Partners, the investment manager of Plaintiff Hawaii Annuity Trust, cited this risk as a factor justifying the stock's below-market price-earnings multiple.
- **Analyst comments in the days following each challenged statement.** The Court held that it was plausible at the pleading stage to allege that a reasonable investor could have understood the February 24, 2006 statement to mean that no new data had been requested by the FDA, and could have understood the October 31, 2006 statement to mean that Sanofi had submitted no new data to the FDA. I reviewed analyst reports issued just after each statement to learn whether investment professionals did in fact form these mistaken impressions from Sanofi's statements. None of the 19 analysts who issued a report in the wake of the February 24 challenged statement wrote that the FDA did not request new data from Sanofi. Likewise, only one of the 20 analysts writing in the wake of the October 31 challenged statement appears not to have heard Defendant Spek's "in this respect"

qualification about what new data the Company did not submit to the FDA at that time (limiting the remark to data from new additional clinical trials).

## **II. QUALIFICATIONS AND REMUNERATION**

7. I am Chair of the Global Securities and Finance Practice and a Senior Vice President at NERA Economic Consulting (“NERA”), a firm that employs several hundred consulting economists who operate out of more than 20 offices worldwide.

8. Over the last 21 years I have been an economic consultant in hundreds of matters involving securities and financial economics. I have addressed issues of market efficiency, class conflict, materiality, damages, settlement prediction and claiming rates in investor litigation alleging material misrepresentations and omissions in a wide range of industries. At least nine other securities class actions that I consulted on involved FDA-related allegations.

9. Before joining NERA in 1992, I was a Vice President of the American Stock Exchange (the “Amex”). As head of the Research Department, I was responsible for research pertaining to listing and Consolidated Tape order flow. Prior to joining the Amex in 1980, I taught economics at the State University of New York at Stony Brook and Swarthmore College. Previously, I had been a researcher at the National Bureau of Economic Research, Inc. I have a B.A. with Great Distinction in Economics from Stanford University, where I was elected to Phi Beta Kappa, and an M.A. and Ph.D. in Economics from Harvard University. I have testified at federal jury trials, an exchange enforcement proceeding, arbitrations, and state court hearings. My curriculum vitae are attached as **Appendix 1**.

10. NERA is being compensated for its work at our standard hourly billing rates plus expenses. My compensation is without regard to the substance of my testimony or the outcome of this litigation. My billing rate in this matter is \$645 per hour. The hourly billing rates of other staffers who worked on this project range from \$95 to \$645.

## **III. MATERIALS CONSIDERED**

11. See Appendix 2.

## IV. RELEVANT FACTS

### A. Sanofi's New Drug Application for Rimonabant: A Brief Chronology

12. Sanofi submitted a New Drug Application ("NDA") to the FDA in April 2005 for rimonabant, a "first-in-class" weight loss drug. During the purported class period, February 20, 2006 through June 13, 2007, rimonabant was also referred to as Acomplia (its brand name in Europe) and Zimulti (its proposed brand name in the US).<sup>4</sup>

13. After trading hours on February 17, 2006, Sanofi announced its receipt of two letters from the FDA regarding the NDA: an approvable letter for weight management from the Division of Metabolism and Endocrinology Products, and a non-approvable letter for smoking cessation from the Division of Anesthesia, Analgesia and Rheumatology Products.<sup>5</sup>

14. On February 24, 2006, following its same-day announcement of fiscal year 2005 earnings, the Company held a conference call with analysts.<sup>6</sup>

15. On June 21, 2006 the EMEA, the FDA's counterpart in Europe, approved Acomplia following an April 28, 2006 favorable recommendation from CHMP, the European equivalent of an Advisory Committee.<sup>7</sup>

16. On October 31, 2006, in the press release announcing 3Q06 earnings, Sanofi also stated, "Regarding the ongoing review of rimonabant(R) in the United States, the company has submitted on October 26, 2006 the complete response to the approvable letter received from the

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<sup>4</sup> First Amended Complaint for Violation of Securities Laws, filed July 28, 2010 ("FAC"), ¶¶3-6.

<sup>5</sup> Press Release, Sanofi-Aventis, Sanofi-aventis Received from the FDA an Approvable Letter for Rimonabant for Weight Management and a Non Approvable Letter for Smoking Cessation, PR Newswire (U.S.), Feb. 17, 2006, 7:59 p.m. Factiva, the source I use for news, has archived stories discussing the news earlier on in the day. The earliest story is from 4:26 p.m. on February, 17, 2006. See UPDATE 3-US gives Sanofi weight-loss drug conditional OK, Reuters News, Feb. 17, 2006.

<sup>6</sup> Press Release, Sanofi-Aventis, Sanofi-aventis Reports Strong Growth of 25.7% in 2005 Adjusted EPS(1); Nearly 90% of synergies delivered by end 2005; Dividend increased by 26.7%, PR Newswire (U.S.), Feb. 24, 2006, 7:30 a.m.; Q4 2005 Sanofi-Aventis Earnings Conference Call – Final, Voxant FD (FAIR DISCLOSURE) WIRE, Feb. 24, 2006.

<sup>7</sup> Sanofi's Acomplia Approved For Sale In EU, Dow Jones Int'l News, June 21, 2006, 11:46 a.m.; Press Release, Sanofi-Aventis, Acomplia(R) (Rimonabant) Recommended for Approval in the European Union, PR News Europe, Apr. 28, 2006, 5:54 a.m.

FDA on February 17, 2006.”<sup>8</sup> Later that day, the Company held a conference call with analysts.<sup>9</sup>

17. On December 8, 2006, Sanofi announced that the FDA considered its response to be a complete Class 2 response, and that the new action date (a.k.a. Prescription Drug User Fee Act or “PDUFA” date) was April 26, 2007.<sup>10</sup>

18. On February 12, 2007, Sanofi provided an update on its rimonabant NDA, announcing that the PDUFA date had been moved three months to July 27, 2007 and that the Company had submitted the results of its Serenade clinical study (involving diabetic patients) for consideration in the pending NDA.<sup>11</sup>

19. On March 26, 2007, Sanofi announced that the FDA had scheduled an Advisory Committee (“AdCom”) public hearing on rimonabant for June 13, 2007.<sup>12</sup>

20. On June 11, 2007, the FDA posted briefing documents for the upcoming meeting to its website, [www.fda.gov](http://www.fda.gov).<sup>13</sup> Included among these was a document stating the FDA’s conclusion that there was a statistically significant link between rimonabant and suicidality.<sup>14</sup>

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<sup>8</sup> Press Release, Sanofi-Aventis, Sanofi-aventis Announces Third Quarter Sales and Earnings for 2006: Sales Growth of 2.6% on a Comparable Basis(1); Adjusted EPS Growth of 15.0%, or 7.5% Excluding Selected Items(3), PR Newswire (U.S.), Oct. 31, 2006, 9:31 a.m.

<sup>9</sup> Q3 2006 Sanofi-Aventis Earnings Conference Call – Final, Voxant FD (FAIR DISCLOSURE) WIRE, Oct. 31, 2006.

<sup>10</sup> Press Release, Sanofi-Aventis, Rimonabant Update in the United States, PR Newswire (U.S.), Dec. 8, 2006, 2:00 a.m.

<sup>11</sup> Press Release, Sanofi-Aventis, Rimonabant USA: Update, Feb. 12, 2007, available at [http://en.sanofi.com/Images/14376\\_070212\\_pdf\\_rimonabant.pdf](http://en.sanofi.com/Images/14376_070212_pdf_rimonabant.pdf). Previously, on December 5, 2006, the Company announced the positive results of the Serenade clinical study in diabetic patients. Sanofi’s Acomplia Data Show Diabetes Potential-Analyst, Dow Jones Int’l News, Dec. 5, 2006, 4:31 a.m.

<sup>12</sup> Press Release, Sanofi-Aventis, Rimonabant USA: Update; Sanofi-aventis Acknowledges FDA Announcement of an Advisory Committee Meeting for rimonabant, PR Newswire, Mar. 26, 2007, 8:35 a.m.

<sup>13</sup> FDA, FDA Briefing Document, NDA 21-888, Zimulti (rimonabant) Tablets, 20 mg, Sanofi Aventis, Advisory Committee – June 13, 2007, (“FDA Brief” or the “Brief”), available at <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4306b1-fda-backgrounder.pdf>; see also FDA: Sanofi Weight-Loss Drug Increases Suicidality, Dow Jones News Service, June 11, 2007, 10:12 a.m.

<sup>14</sup> It is my understanding that Sanofi and the FDA may differ in their assessment of whether there is in fact a causal link between rimonabant and suicidality. Unless otherwise stated, when I use the term “suicidality finding” or “causal link” in this report, I am referring to the statement by an FDA staffer that “[c]ompared to placebo, 20 mg rimonabant statistically significantly increased suicidality based on analyses both of incidence rates and person-years.” FDA Brief, Statistical Review of Safety: Division of Biometrics II at 8. I have not formed or been asked to form an opinion on the validity of that finding.

21. On the afternoon of June 13, 2007, following a day of presentations, the members of the AdCom (the “Panel” or the “AdCom panel”) voted unanimously not to recommend rimonabant for approval.<sup>15</sup>

## **B. The Challenged Statements**

22. On November 13, 2007, the first securities class action lawsuits were filed against Sanofi and on April 29, 2008, Plaintiffs filed a Consolidated Complaint for Violations of Securities Laws (the “Consolidated Complaint”). The Court dismissed the Consolidated Complaint on September 25, 2009 for failure to state a claim. Plaintiffs then filed the First Amended Complaint for Violations of Securities Laws (the “Amended Complaint” or “FAC”) on July 28, 2010, alleging that Defendants had made false and misleading statements about rimonabant and the Company’s communications with the FDA regarding the drug. Defendants filed a Motion to Dismiss the Amended Complaint on September 27, 2010.

23. On March 30, 2011, the Court ruled on Defendants’ motion to dismiss the FAC. In so doing, it left standing two challenged statements:

- Statement by Defendant Le Fur in the February 24, 2006 conference call: “So as you know, in the non-approvable letter that we received on Rimonabant, the FDA asked us to perform an additional clinical study in smoking cessation. But in the approvable letter, no additional trial in obesity has been requested by the agency and we will meet the FDA in the coming weeks to address all remaining issues.”<sup>16</sup>
- Statement by Defendant Spek in the October 31, 2006 conference call: “We have received an approvable letter and usually, and also in this case, an approvable letter contains questions. We have answered to those questions and as the approvable letter did not ask for new additional clinical trials, consequently it is easier for me to say that we have not submitted new data in this respect.”<sup>17</sup>

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<sup>15</sup> Lisa Richwine, UPDATE 2-U.S. panel rejects Sanofi obesity drug, Reuters News, June 13, 2007, 4:25 p.m.; Press Release, Sanofi-Aventis, FDA Advisory Committee Did Not Recommend Approval of Rimonabant (ZIMULTI(R)) for Use in Obese and Overweight Patients With Associated Risks Factors, PR Newswire (U.S.), June 13, 2007, 6:25 p.m.

<sup>16</sup> Q4 2005 Sanofi-Aventis Earnings Conference Call – Final, Voxant FD (FAIR DISCLOSURE) WIRE, Feb. 24, 2006.

<sup>17</sup> Q3 2006 Sanofi-Aventis Earnings Conference Call – Final, Voxant FD (FAIR DISCLOSURE) WIRE, Oct. 31, 2006.

24. The Court held it was plausible that the February 24, 2006 statement was a misstatement or actionable omission because “[a]n investor could have understood this statement to mean that, with respect to rimonabant as an obesity drug, the FDA made no other requests and/or that the FDA approval process was on track without any major concerns.” Noting that this statement did “specifically address[] the content of the February 17, 2006 FDA letter,” the Court added that “disclosing the omitted facts may have provided a more complete picture of rimonabant’s approval status, and thus significantly contributed to the total mix of information available to investors.”<sup>18</sup>

25. The Court held it was plausible that the October 31, 2006 statement was a misstatement or actionable omission because “it may not have been obvious to a reasonable investor that [S]anofi was submitting new data to the FDA” and that “[b]y answering ‘no,’ Spek’s response could have led a reasonable investor to believe that [S]anofi had not submitted new data on some issue that concerned the FDA.”<sup>19</sup> The Court then stated that “the alleged omitted facts are sufficiently related to this statement that disclosing such information may have significantly contributed to the total mix of information available to investors . . . and thereby that [S]anofi may have come under a duty to disclose some or all of the omitted facts.”<sup>20</sup>

26. Both challenged statements concern the provision of data to the FDA, including Dr. Kelly Posner’s suicidality codings (the “Posner Codings”). With regard to the February 24 statement, the Court wrote that disclosure of the FDA’s *request* for an independent, formal assessment of suicidality “may have provided a more complete picture of rimonabant’s approval status.”<sup>21</sup> As to the October 31 statement, the Court’s concern was with the adequacy of Defendants’ disclosure regarding the *submission* of “additional data” to the FDA.<sup>22</sup>

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<sup>18</sup> Order at 564-65.

<sup>19</sup> Order at 568-69. The Court observed that Plaintiffs alleged the statement to be “false and misleading” on account of four omitted facts: “(a) the FDA had requested and [S]anofi had produced additional patient records that showed a ‘signal’ or possible causal relationship between rimonabant and suicidality; (b) the FDA required Defendants to reassess the data from the clinical trials to investigate for other cases of suicidality and Dr. Kelly Posner commenced an independent, formal assessment; (c) Defendants submitted new data to the FDA, specifically the results of Dr. Posner’s suicidality assessment; (d) the independent assessment showed a statistically significant link between rimonabant and suicidality.” Order at 568 (quoting FAC ¶67) (internal citations omitted).

<sup>20</sup> Order at 569.

<sup>21</sup> Order at 564-65.

<sup>22</sup> Order at 568.

27. What the Court could not have known (or perhaps even have considered, at the motion to dismiss stage) is that Plaintiffs *have no factual basis* for alleging an omission of statistical analysis from Dr. Posner. The analysis that Dr. Posner provided to Sanofi and that Sanofi in turn submitted to the FDA on October 26, 2006 was limited to coding and did not include any tests of statistical significance.<sup>23</sup> It was the FDA's statistical analysis of these data, not any statistical analysis by Dr. Posner or her team, that the market learned of on June 11, 2007. As Dr. Posner did not conduct an analysis of the data for statistical significance and the FDA's analysis was not something that Defendants were privy to at the time of the October 31, 2006 statement (indeed, that analysis may not yet have even commenced),<sup>24</sup> Defendants surely could not have disclosed either, nor is there any credible allegation to the contrary.

## **V. EVENT STUDY EVIDENCE FOR THE CORRECTIVE DISCLOSURE STRONGLY ARGUES AGAINST CLASS CERTIFICATION**

28. Plaintiffs assert materiality when referring to the alleged misrepresentations but omit it from their statement of what they must establish to have a presumption of reliance (market efficiency is all they mention)<sup>25</sup> and offer no evidence explicitly in support of it. That said, Sanofi's June 13, 2007 price drop and heavy volume figure prominently in their motion, which describes this market activity as being in response to the revelation of material adverse information that Defendants had failed to disclose:

“[t]he Complaint alleges that, during the Class Period, defendants failed to disclose material adverse information regarding the FDA approval process and serious adverse effects associated with the use of rimonabant. *See, e.g.*, ¶¶ 3–15. While these risks were known to

<sup>23</sup> *See* Declaration of Dr. Kelly Posner, Apr. 24, 2012

<sup>24</sup> Internal communications between the Company and the FDA in December 2006 indicate that at the time of the October 31, 2006 statement, the FDA did not have all the information it deemed necessary to make a full assessment of rimonabant's link with suicidality. In mid-December, the FDA requested an unedited copy of the instructions used to perform the Posner Codings and the unedited spreadsheet that Dr. Posner sent to Sanofi. *See* Dec. 11, 2006 and Dec. 12, 2006 emails from Patricia Madara, SA-00021871-00021872. The FDA also asked on December 15 for several pieces of information relating to suicidality, including a table identifying all 89 subjects identified in the Posner Codings as possibly or definitely suicidal and a breakdown of the narratives sent to Dr. Posner by study and by treatment. Dec. 15, 2006 email from Patricia Madara, SA-00022050-00022051. On December 22, Sanofi submitted a complete written response to answer the FDA's questions. Dec. 22, 2006 FDA Submission to Mary Parks, SA-00103169-00103179. The FDA also submitted a series of questions to Sanofi on December 22, but told Sanofi on December 28 that the Company's “previous submissions have answered all the questions we had asked” in the December 22 request and that no response was necessary. Dec. 22, 2006 and Dec. 28, 2006 emails from Patricia Madara, SA-00022566-00022567.

<sup>25</sup> Renewed Class Cert Motion at 19-20.

defendants by no later than February 20, 2006, it was not until June 13, 2007, when the FDA Advisory Committee refused to recommend approval of rimonabant for the treatment of obesity, that it was disclosed there was a link between rimonabant and suicidality. ¶¶ 16 – 18. Upon the revelation of these facts, the price of Sanofi’s stock and ADRs fell dramatically on heavy trading volume and continued to drop sharply over the following trading days.”<sup>26</sup>

In this section, I establish using event study evidence that the omitted information was *not* material when disclosed and that neither alleged misstatement was misleading.

### **A. Event Study Methodology: An Overview**

29. In forming an opinion about how a particular piece of news affects the price of a security, financial economists conduct what is called an “event study.” An event study is a rigorous statistical technique for determining the magnitude and statistical significance of the company-specific component of security price change, i.e., the change not explainable by market or industry factors. Event study analysis is perhaps the foremost example of the scientific method in financial economics, with hundreds if not thousands of academic papers published on the subject in the decades since it was first advanced in 1969.<sup>27</sup> Expert testimony based on properly conducted event studies has been admitted in numerous court proceedings.<sup>28</sup> The event study has become a fixture in securities litigation, and in the economics and legal literature related to that topic.<sup>29</sup>

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<sup>26</sup> Renewed Class Cert Motion at 1-2 (internal citations omitted).

<sup>27</sup> Eugene F. Fama, Lawrence Fisher, Michael C. Jensen & Richard Roll, The Adjustment of Stock Prices to New Information, International Economic Review 1-21, Vol. 10, No. 1 (Feb. 1969).

<sup>28</sup> See In re Executive Telecard, 979 F. Supp. 1021, 1021 (S.D.N.Y. 1997); see also Goldkrantz v. Griffin, No. 97 Civ. 9075 (DLC), 1999 WL 191540, at \*13-14 (S.D.N.Y. Apr. 6, 1999) (granting defendants’ summary judgment motion due to plaintiffs’ failure to contest defendants’ event study analysis); In re Seagate Tech II Sec. Litig., 843 F. Supp. 1341, 1368-69 (N.D. Cal. 1994) (accepting some of defendants’ event studies, and dismissing certain claims on that basis, but ruling that defendants’ other event studies were inadequate and denying their motion for summary judgment with regard to those issues; the court also found plaintiffs’ event studies lacking and therefore denied plaintiffs’ cross-motion for summary judgment).

<sup>29</sup> See, e.g., Alexander, Janet Cooper, The Value of Bad News, 41 UCLA L. Rev. 1421, 1421-69 (1994); Bradford Cornell & R. Gregory Morgan, Using Finance Theory to Measure Damages in Fraud on the Market Cases, 37 UCLA L. Rev. 883, 883-84 (1990); Alan J. Cox & Jonathan Portes, Mergers in Regulated Industries: The Uses and Abuses of Event Studies, 14 Journal of Regulatory Economics, Kluwer Academic Publishers 281-304 (1998); Fischel, Daniel R., Use of Modern Finance Theory in Securities Fraud Cases Involving Actively Traded Securities, 38 Bus. Law. 1 (1982); Jared T. Finkelstein, Note, Rule 10b-5 Damage Computation: Application of Financial Theory to Determine Net Economic Loss, 51 Fordham L. Rev. 838 (1983); Jon Koslow, Note, Estimating Aggregate Damages in Class Action Litigation Under Rule 10b-5 for Purposes of Settlement, 59 Fordham L. Rev. 811, 826-42 (1991); Philip J. Leas, Note, The Measure of Damages in Rule 10b-5 Cases Involving Actively Traded Securities, 26 Stan. L. Rev. 371, 385-96 (1974); Jonathan R. Macey, et al., Lessons from Financial Economics: Materiality,

30. The following is a succinct description of what an event study entails:

Event studies of the type used in litigation rely on two well-accepted principles: first, the semi-strong version of the Efficient Market Hypothesis, which states that stock prices in an actively traded security reflect all publicly available information and respond quickly to new information; and, second, the price of an efficiently traded stock is equal to the present discounted value of the future stream of free cash flow. Consequently, the stock price impacts of an event can reveal the effects of the event on future cash flows if the following conditions are present:

1. The event is a well-defined news item.
2. The time that the news reaches the market is known.
3. There is no reason to believe that the market anticipated the news.
4. It is possible to isolate the effect of the news from market, industry, and other firm-specific factors simultaneously affecting the firm's stock price.

The procedure for performing an event study has several well-defined steps:

First, one estimates a predicted stock price return, or percentage change, from the day before the news reaches the market to the day the stock price assimilates the news. In doing this estimation, one uses a model that takes into account market and industry effects on stock price returns.

Next, the predicted return is subtracted from the actual return to compute what is called the excess return. If the excess return is calculated as the sum of individual excess returns over a number of periods (usually individual trading days), the difference between the actual and predicted returns summed over all these periods is called the cumulative excess return (or CAR).

Typically, the predicted return does not exactly equal the actual return even when no event has occurred. To determine whether the difference between the actual and the predicted return (the CAR) is just due to chance, the CAR is tested for statistical significance, as described in a later section of this paper.

The final step, if necessary, involves computing the relevant magnitude of the event. To do this, one calculates the change in stock price or capitalized value of the firm implied by the estimated CAR and thus attributable to the event in question.<sup>30</sup>

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Reliance, and Extending the Reach of Basic v. Levinson, 77 Va. L. Rev. 1017, 1021-28 (1991); A. Craig MacKinlay, Event Studies in Economics and Finance, 35 Journal of Economic Literature 13-39, March 1997; Mark L. Mitchell & Jeffrey M. Netter, The Role of Financial Economics in Securities Fraud Cases: Applications at the Securities and Exchange Commission, 49 Bus. Law. 545-90(1994).

<sup>30</sup> David I. Tabak & Frederick C. Dunbar, Materiality and Magnitude: Event Studies in the Courtroom, Litigation Services Handbook: The Role of the Financial Expert, John Wiley & Sons, Inc., 3rd ed. (2001) Chapter 19, at 2-3 (internal citations omitted).

31. To obtain an event day's "expected" or "predicted" return, financial economists estimate a "market model." This is a linear equation fit to historical data by means of regression analysis. The data involve the periodic (typically, daily) returns (i.e., percent or logarithmic changes) of a particular security (the "dependent variable") and the same-period returns of a broad market and/or industry index (the "independent variables").<sup>31</sup> In shareholder class actions, market models are typically estimated over a time span that precedes the class period or that falls within it but excludes the event days of interest. The estimated market model (a regression line) is then used in conjunction with index returns for any given day to find that day's predicted return. The market model's explanatory power is measured by its  $R^2$ : the variance of the security's predicted returns divided by the variance of the security's total returns. The difference between a day's actual return and predicted return is the day's excess or "abnormal" return.<sup>32</sup>

32. The role of a market model in an event study is two-fold: to predict the security's return *absent company-specific news* on days when such news enters the market ("event days"), and to determine the uncertainty surrounding that prediction (the model's standard error). A security's abnormal return on an event day is a first-pass estimate of how company-specific news affected the price.<sup>33</sup> The ratio of that abnormal return to the model's standard error equals the

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<sup>31</sup> Ordinary least squares regression fits a line through the data; the line is positioned (i.e., its coefficients are chosen) so as to minimize the sum of squared differences between the security's actual returns and the corresponding model-generated or predicted returns.

<sup>32</sup> To meet Daubert's standard for admissibility an event study must remove from a stock's actual price change the change estimated to have been caused by market and industry developments, as opposed to company-specific news. "Those principles—when applied within the damages valuation context—simply require elimination of that portion of the price decline that is the result of forces unrelated to the wrong. Such forces can be broadly categorized into: (1) company risk—the unique risk that is peculiar to the particular stock at issue, and (2) market risk—the risk associated with market wide variations generally." In re Executive Telecard, 979 F. Supp. at 1025 (internal citations omitted).

<sup>33</sup> Except in very unusual circumstances, securities that trade in an efficient market are expected to fully impound material new public information within a day and generally do so much more quickly. When the news is complex and momentous, however, an efficiently traded stock may take more than a day to fully digest the new information. To allow for this possibility, it is my standard practice and that of many other finance experts to test the significance of daily abnormal returns not just on the first day that news enters the market but on successive days as well, and to allow the event window (i.e., the period over which cumulative abnormal price change in connection with an event is measured and its statistical significance is assessed) to run through the last consecutive day on which the stock's daily abnormal return is statistically significant and unrelated news of a potentially material nature has not been disseminated. If abnormal return on the day when the news of interest enters the market is not statistically significant, the event window terminates that day. Some have proposed sharply elevated volume as another reason to allow an event window to run more than one day. See Dmitry Krivin, Robert Patton, Erica Rose, & David Tabak, Determination of the Appropriate Event Window Length in Individual Stock Event Studies, NERA Working Paper, Nov. 4, 2003.

return's "t-statistic" ("t-stat"). The higher the t-stat in absolute value, the less likely it is for an abnormal return of that magnitude to occur strictly by chance (i.e., absent company-specific news).

### **B. A Fully Corrective Disclosure Occurred On June 11, 2007**

33. The first step in my event study is to determine the date by which all of the allegedly relevant truth became public.

#### **i. Corrective Information Entered the Market on June 11, 2007**

34. Plaintiffs move for a class period that extends from February 20, 2006 through June 13, 2007.<sup>34</sup>

35. No purchaser of Sanofi securities could possibly have been damaged after the facts credibly alleged to have been misrepresented or omitted were fully disclosed. As explained below, this happened on June 11, 2007: two trading days before Plaintiffs claim.

36. In their motion to certify the class, Plaintiffs state, "At the [June 13, 2007 FDA Advisory Committee's] public hearing it was revealed that there was a causal link between rimonabant and suicidality. Based on this information, the FDA Advisory Committee voted unanimously not to recommend approval of rimonabant for the treatment of obesity *as a result of* concerns about suicidal ideation associated with the use of the drug."<sup>35</sup> This claim that the revelation occurred on June 13, 2007, which Plaintiffs assert in support of their proposed Class Period end date and which I therefore term their Disclosure Claim, is false.

37. The Disclosure Claim is false, because the information in question was disclosed on June 11. As a wealth of evidence makes clear, the FDA's finding of a statistically significant relationship between rimonabant and suicidality was made public not during the AdCom meeting of June 13, 2007 but in briefing documents posted to the FDA website, [www.fda.gov](http://www.fda.gov), on the morning of June 11, 2007 and then widely discussed in the press and by analysts. The "Conclusions and Recommendations" paragraph of the "Statistical Review of Safety" section of the FDA Briefing Document states:

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<sup>34</sup> Renewed Class Cert Motion at 1. Counsel has instructed me that the relevant start date is February 24, 2006.

<sup>35</sup> Renewed Class Cert Motion at 6 (emphasis added) (internal citations to FAC ¶¶79-90 omitted).

The incidence of suicidality – specifically suicidal ideation – was higher for 20 mg rimonabant compared to placebo. Similarly, the incidence of psychiatric adverse events, neurological adverse events and seizures were consistently higher for 20 mg rimonabant compared to placebo. Tables 1 to 3 below display risk estimates and the 95% confidence intervals for the overall population, the obesity population and the obese diabetic population for the incidence of suicidality, psychiatric and neurological events, and seizures, respectively.

...

Compared to placebo, 20mg rimonabant statistically significantly increased suicidality based on analyses both of incidence rates and person-years.<sup>36</sup>

38. The FDA performed these statistical analyses using the Posner Codings. The FDA Brief describes these data and notes that the Agency had asked Sanofi to obtain these data for it and that Sanofi had done so and submitted them to the FDA.<sup>37</sup> All of these allegedly “omitted facts” were revealed to the market in the FDA Brief on June 11, 2007.

39. To ascertain whether the FDA Brief actually came to the attention of the investment community (as it surely would have if the market were efficient), I reviewed news stories and analyst reports about Sanofi from June 11 and June 12 for mentions of suicide or suicidality.

#### **a. Scores of June 11 – 12 News Stories Noted the Brief’s Suicide-Related Findings**

40. I searched Factiva for all Sanofi/rimonabant items on June 11 or June 12, 2007. Of the 223 English-language articles thus identified, 78 contain a word beginning with “suicid.” In 29 instances, that word appears in the headline or lead paragraph.

<sup>36</sup> See FDA Brief, Statistical Review of Safety: Division of Biometrics II, at 3, 8.

<sup>37</sup> After taking steps to update its database of adverse events with more information, Sanofi prepared and submitted so called patient-narratives to Dr. Posner’s team. Of the total 1201 patient-narratives, Dr. Posner’s team blindly classified 91 cases as either possibly or definitely suicidal. Columbia University’s C-CASA Suicidality Assessment, developed by Dr. Posner, has the following categories: 1 Complete suicide, 2 Suicide attempt, 3 Preparatory acts towards imminent suicide, 4 Suicidal ideation, 5 Self-injurious behavior, intent unknown, 6 Not enough information (fatal), and 9 Not enough information (non-fatal). Of these, categories, one through four fall into the “definitely” suicidal spectrum according to the FDA, while five, six and nine are “possibly” suicidal. Of the 91 cases, 20 were in placebo, while the rest were occurred in patients taking 5 mg or 20 mg rimonabant. The majority of cases (58) were classified as suicidal ideation (i.e. passive thoughts about wanting to be dead or active thoughts about killing one’s self, not accompanied by preparatory behavior). There were no cases of complete suicide and of the eleven suicide attempt or preparatory acts toward imminent suicide events, the majority (7) were in the placebo group. FDA Brief, Clinical Review of Safety and Efficacy: Division of Metabolism and Endocrinology Products, at 25-27.

41. The first article to mention suicidality, headlined “FDA: Sanofi Weight-Loss Drug Increases Suicidality,” was disseminated by *Dow Jones News Service* on June 11 at 10:12 a.m. Eastern Time (“ET”) in the U.S. Other stories followed throughout that day and into the next. Here is a sampling:

- **“In briefing documents posted to its Web site Monday, the FDA said the 20-milligram dose of Acomplia was ‘associated with statistically and clinically significant weight loss.’** However, the FDA said it was concerned about an increase in psychiatric side effects as well as seizures... The FDA reviewed clinical studies of the drug as well as post-marketing reports of the drug from Europe. **The agency said the 20-milligram dose of Acomplia ‘statistically, significantly increased suicidality’ compared to placebo or a fake drug.”** Jennifer Corbett Dooren, FDA: Sanofi Weight-Loss Drug Increases Suicidality, *Dow Jones News Service*, June 11, 2007, 10:12 a.m. ET (emphasis added).
- **“People who took a Sanofi-Aventis SA obesity pill in clinical trials were more likely to report suicidal thoughts or actions...** Suicidal thoughts were reported for 0.63 percent of Zimulti patients and 0.38 percent of placebo patients, Sanofi said in a separate summary. One Zimulti patient actually committed suicide. ... The FDA will ask outside advisers if they believe Zimulti increases suicidal behavior, other psychiatric problems, neurological problems and seizures, and if the drug should be approved... The agency usually follows panel recommendations. Some industry analysts said it was unclear how the panel would decide.” Lisa Richwine, UPDATE-3-US FDA sees suicidal behavior with Sanofi drug,” *Reuters News*, June 11, 2007, 10:51 a.m. ET (emphasis added).
- **“The [FDA] said a detailed meta-analysis of the suicidality data will be presented to the advisory panel Wednesday, but noted that patients on rimonabant were twice as likely to report an increase in ‘suicidality’...** ‘We anticipate that much of the discussion at the advisory committee meeting will center on the relationship between rimonabant and depression, and on the methodology, results and interpretation of FDA’s meta analytic assessment of suicidality from completed rimonabant studies,’ the FDA said in a letter to panel members.” Jennifer Corbett Dooren, 2nd UPDATE: FDA Says Weight-Loss Drug Increases ‘Suicidality’, *Dow Jones News Service*, June 11, 2007, 2:36 p.m. ET (emphasis added).
- **“... [A]gency staffers raised concerns about an increased rate of psychiatric adverse events among patients taking Acomplia, including depression, anxiety and insomnia. About 26 percent of patients on Acomplia reported such events, compared with 14 percent of patients on placebo. FDA also drew attention to a possible link between Acomplia and suicidal behavior.”** Matthew Perrone, FDA has concerns about suicide, depression and other risks tied to Sanofi-Aventis’ Acomplia, *Associated Press*, June 11, 2007, 4:37 p.m. ET (emphasis added).

- “Acomplia Increases Suicidality, FDA Says

**The Food and Drug Administration said that proposed Sanofi-Aventis weight-loss drug Acomplia was effective at promoting weight loss but also increased the rate of suicidal thoughts and behaviors.**” Tim Annett, The Evening Wrap: Judging Gonzales, Wall St. J. Online, June 11, 2007 (emphasis added).

- “More disturbingly, a meta-analysis of some 13 clinical trials conducted by Sanofi-Aventis found that **a greater number of events linked to ‘suicidality’—suicidal behaviour and thought rather than actual suicide—were recorded among patients taking the 20-mg dose than those taking the 5-mg dose or those administered placebos.** More specifically, some 46 separate incidences of suicidal thought or behaviour were recorded in the Acomplia 20-mg group, compared with eight in the 5-mg group and 20 in the placebo group. There were, however, more cases of attempted suicide in the placebo group (seven) than in the Acomplia 20-mg group (four).” Mitra Thompson, Suicidal-Thoughts Link Threatens Sanofi-Aventis’s Acomplia After New U.S. FDA Review, Global Insight Daily Analysis, June 12, 2007 (emphasis added).
- “... [Acomplia] was effective at promoting weight loss but appeared to **double the rate of suicidal thoughts and behavior.**” Jennifer Corbett Dooren, Obesity Pill From Sanofi Gets Review, Wall St. J., June 12, 2007 (emphasis added).

#### **b. Many Analyst Reports from June 11 and 12 Remarked on the Brief’s Suicide-Related Findings**

42. The FDA’s suicidality analyses were also the subject of numerous analyst reports published over the two-day period. Eleven analysts published Sanofi-specific English-language reports on June 11 or 12, and ten of them contained rimonabant commentary. *All* ten mention the findings, as detailed in **Exhibit 1**.<sup>38</sup> Illustrative mentions include the following:

- “FDA published briefing documents on Zimulti (formerly Acomplia) ahead of the July 13th panel (this Wednesday). Increased ‘suicidality’ looks to be the major FDA concern . . . . However the **FDA requested a deeper analysis** of the side-effect data to identify how many patients experienced a potential signal – ‘**suicidal ideation**’ defined as passive thoughts about killing oneself, not accompanied by preparatory behavior . . . . This analysis, conducted over the last few months, has revealed a **significant signal with a suicidality rate of 0.68% in the Zimulti 20mg arm versus 0.41% in the placebo arm.**” JP Morgan, FDA Focus on Zimulti Suicidality Risk – ALERT, June 11, 2007 (emphasis added).

<sup>38</sup> My team obtained analyst reports from counsel and purchased additional ones from Thomson Investtext and Reuters Knowledge. They have reviewed all company-specific, non-technical, English reports on these dates.

- “Yesterday evening, the FDA published on its website the briefing document for Acomplia that will be presented to the advisory committee experts on 13 June. **This chunky document (88 pages) is mainly devoted to the effects that rimonabant has on the central nervous system, its neurological and psychiatric side effects (e.g. depression, suicidal thoughts and behaviour,** anxiety, exacerbation of multiple sclerosis flares)... After reading this document, as well as the accompanying letter, we think it is very difficult to tell what conclusion the advisory committee will draw... **The experts are bound to focus on the risk of suicide that seems to be linked to taking Acomplia.** The FDA does not hide the fact that it is concerned about the consequences that taking the product has on central cannabinoid receptors.” Raymond James, Acomplia/Zimulti: a ‘neurological’ dossier that is a first for an obesity treatment, June 12, 2007 (emphasis added).
- “Independent blinded assessment shows Zimulti doubles Suicidality — The odds ratio for suicidality from all clinical trials is a statically significant 1.9x higher than placebo. 2 cases of completed suicide have been reported on Zimulti. ... We have previously highlighted our safety concerns of depression and suicide risk in our Citi Investment Research report ‘Mission Acomplia I’, 9/2/06.<sup>39</sup> **Yesterday FDA briefing documents confirmed our suspicions: The approvable letter in 2006 was due to the FDA’s ‘concern about [an] increased frequency of psychiatric adverse events, including suicidality’.**” Citigroup, FDA states Zimulti (Acomplia) doubles suicidality rate in Advisory Committee briefing documents, June 12, 2007 (footnote and emphasis added).

**c. News Stories and Analyst Reports in this Interim Period Identified Columbia University as the FDA’s Suicidality Data Source and Cited Suicidality Concern as a Factor in the FDA’s Issuance of an Approvable Letter**

43. With regards to how the Posner Codings came into being, the FDA Brief states:

“Moreover, review of the preclinical and clinical data raised concern about associations between rimonabant and increased frequencies of psychiatric adverse events, including suicidality, an ill-defined constellation of neurological signs and symptoms, and seizures. Based on these concerns [the FDA’s Division of Metabolism

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<sup>39</sup> “As a result of our in-depth analysis of the safety of Acomplia in obesity, we are still struggling with the safety profile of Acomplia when used to lose weight and are even more cautious on its commercial prospects if it is used in this setting... If Acomplia gains regulatory approval we still see serious safety concerns in the market when millions could take the drug, especially if it is used inappropriately for lifestyle reasons... The prevalence of depression amongst obese patients is estimated at over 20%. However all the RIO trials specifically excluded neurological or psychological illness, a history of two or more episodes of depression, or suicide attempt. Since the trial population is not accurately representative of the target population, the possibility of a suicide in a depressed person who also took Acomplia is raised. Furthermore concomitant use of antidepressants or neuroleptic drugs was not permitted in the RIO trials, but the probability of concomitant use is raised, even if a specific contradiction is forced on to the label. One case of suicide on Acomplia in obesity would be disastrous for Sanofi-Aventis and the FDA, especially in the post Vioxx era.” Citigroup, Mission Acomplia I, Feb. 9, 2006 (internal citation omitted).

and Endocrinology Products (“DMEP”)] sent Sanofi-Aventis an approvable letter in February 2006, requesting that they provide additional data and analyses to more precisely characterize these potential drug-related adverse events. These additional data and analyses [were] submitted by Sanofi-Aventis in October 2006...”<sup>40</sup>

“To investigate a signal for suicidality detected during review of the original NDA submission, DMEP requested that Sanofi-Aventis obtain a formal assessment of suicidality from Dr. Kelly Posner’s group at Columbia University.”<sup>41</sup>

44. Thus, the FDA Brief revealed (1) that the approvable letter sought information regarding suicidality and (2) that the October resubmission included data regarding suicidality.

45. I also reviewed news stories and analyst reports for comments about what prompted the FDA to issue its February 2006 approvable letter and how the FDA obtained the suicidality data underlying its just-released analysis. These are topics of special interest because they speak directly to the alleged omissions. Among my findings:

- “FDA denied Acomplia in 2006 due to suicidality side effects - We have previously highlighted our safety concerns of depression and suicide risk in our report Mission Acomplia I, 9/2/06. Yesterday Food & Drug Administration (FDA) briefing documents confirmed our suspicion: **The approvable letter in 2006 was due to the FDA’s ‘concern about [an] increased frequency of psychiatric adverse events, including suicidality’.**” Citigroup, FDA states Zimulti (Acomplia) doubles suicidality rate in Advisory Committee briefing documents, June 12, 2007 (emphasis added).
- “**As outlined in the approvable letter for Acomplia/Zimulti (rimonabant) from February 2006, the FDA is concerned about the increased frequencies of psychiatric adverse events, including suicidality,** an ill-defined constellation of neurological signs and symptoms, as well as seizures.” WestLB Equity Markets, FDA advisory committee briefing material does not bode well for US approval, June 12, 2007 (emphasis added).
- “The FDA has released early the documents for its Advisory Committee meeting on 13 June. They highlight the efficacy of rimonabant 20mg, **but also focus very much on the CNS risks (depressive disorders, suicidal thoughts, anxiety), which is the reason behind the Feb. 06 approvable letter. The FDA requested a more in-depth analysis of these CNS risks including suicidal behaviour.**” Societe Generale, FDA documents released earlier, highlight CNS side-effects, June 12, 2007 (emphasis added).

<sup>40</sup> FDA Brief, Clinical Review of Safety and Efficacy: Division of Metabolism and Endocrinology Products, at 5.

<sup>41</sup> FDA Brief, Clinical Review of Safety and Efficacy: Division of Metabolism and Endocrinology Products, at 25.

- **“At the agency’s request, sanofi obtained a formal assessment of the potential suicidality of the product from Columbia University researchers.”** FDA Committee to Weigh Suicidality for Sanofi’s Weight Loss Drug, Drug Industry Daily, June 12, 2007, Vol. 6, No. 115 (emphasis added).
- **“However, the FDA is concerned about the drug’s mechanism, and has asked sanofi-aventis to provide additional information on patients, which has then been handed on to a specialist at Columbia [U]niversity, who has rated the patients on a scale of suicidal tendencies.”** IXIS Securities, Suspense continues on rimonabant, June 12, 2007 (emphasis added).

46. The media and analyst report coverage given to the FDA’s suicidality data request and subsequent statistical findings establish that the market had not only been provided with but actually *heard* the corrective information (i.e., that the FDA was interested in exploring a possible link between rimonabant and suicidality) *before* June 13, 2007. Investors would not have had to personally read the FDA Brief to learn of this interest; they could as easily have done so by reviewing Sanofi news or analyst reports on June 11 or 12. Assuming market efficiency, the import of this news *and of the FDA’s findings themselves* would have been fully impounded in the price of the ADS and the ordinary shares *before* the June 13 AdCom meeting.

**ii. New Information About Rimonabant Entered the Market on June 13, 2007, but None of It Was Corrective**

47. Plaintiffs have insisted throughout this litigation that June 13, 2007 is the date of the corrective disclosure.<sup>42</sup> As explained above, my opinion is that June 11, 2007 is when the alleged omissions were cured. Even so, in the interest of completeness, I opine on what did – and did not – happen on June 13.

**a. What Did *Not* Happen on June 13: No New Information Was Disclosed Regarding the Posner Codings, Whether With Respect to the FDA’s Request for these Data from Sanofi, Sanofi’s Submission of these Data to the FDA, or Findings of a Link Between Rimonabant and Suicidality Based on these Data**

48. On June 13, 2007, the 14-member AdCom panel convened for a series of public presentations and deliberations on rimonabant, after which the Panel voted. The three-part question that motivates this section is whether, on June 13, it was newly revealed that Sanofi had

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<sup>42</sup> See FAC ¶¶16, 18, 79, 93-94, 102; Renewed Motion for Class Cert at 2, 6.

been requested to or did submit the Posner Codings (or any such data) to the FDA, or whether any scientific findings based on the Posner Codings were newly disclosed.

49. The AdCom meeting included no disclosure of new information regarding the FDA's February 2006 request for data from Sanofi or Sanofi's October 2006 provision of data to the FDA. Everything that meeting covered concerning this data request and submission was public knowledge on June 11, 2007.

50. With regard to the link between Acomplia and suicidality, two of the three FDA presenters discussed the relationship between rimonabant and suicidality. Only Dr. Amy Egan, whose presentation addressed clinical and safety issues generally, cited findings based on the Posner Codings. Dr. Eric Colman cited week-old post-marketing data from Europe.<sup>43</sup>

51. To determine whether any findings (as opposed to opinions) about suicidality were newly disclosed at the June 13 AdCom meeting, I systematically identified comments relating to suicide or suicidality in the FDA's presentations and compared their substance to what was contained in the FDA Brief (quotes, tables and charts).

52. **Exhibit 2** summarizes this comparative analysis. It demonstrates that the key June 13 statements involving on the Posner Codings have a corresponding entry in the June 11 FDA Brief.<sup>44</sup> Thus:

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<sup>43</sup> At the AdCom meeting, the FDA presented new post-marketing data on psychiatric side events (including suicidality) from Europe that it had "just obtained within the last week and, in some cases, actually yesterday." Transcript, Dep't of Health and Human Svcs. FDA Center for Drug Evaluation and Research, NDA 21-88 Zimulti (rimonabant), Sanofi-Aventis, June 13, 2007 ("AdCom Tr.") at 294. These data were timely disclosed, and there is no allegation to the contrary. Note that the AdCom transcript is accessible online in four parts. See AdCom Tr., available at <http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4306t1-Part1.pdf> (pages 1-99); <http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4306t1-Part2.pdf> (pages 100-199); <http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4306t1-Part3.pdf> (pages 200-299); <http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4306t1-Part4.pdf> (pages 300-386).

<sup>44</sup> Dr. Egan's June 13 presentation identified two suicides that were not noted in the FDA's June 11 Brief. Neither suicide figured in the Posner Codings because they were not part of the data that Sanofi was asked to have Dr. Posner assess. Moreover, Sanofi was not informed of them until May 2007. See Exhibit 2.

Dr. Egan's June 13 Presentation	June 11 FDA Brief
<p>"A total of 1201 patient narratives were prepared by Sanofi and submitted to Dr. Posner's group for a blinded analysis. The analysis identified 91 cases of either definitely or possibly suicidal." AdCom Tr. at 283, Slide 46.</p>	<p>"A total of 1201 patient-narratives were assessed in a strictly blinded manner by the Columbia University group. Ninety-one (91) cases were classified as either possibly (Columbia categories 5, 6, or 9), or definitely (Columbia categories 1, 2, 3, or 4) suicidal...." FDA Brief, <u>Clinical Review of Safety and Efficacy: Division of Metabolism and Endocrinology</u>, at 26.</p>
<p>"[T]he total number of suicidality cases contributing to the analyses is 74" AdCom Tr. at 284, Slide 48.</p>	<p>"Fourteen studies contributed to the analysis which had a total of 74 suicidality cases (1<sup>st</sup> randomization) . . . ." FDA Brief, <u>Statistical Review of Safety: Division of Biometrics II</u>, at 7.</p>
<p>"The odds ratio for the incidence of suicidality, rimonabant 20 version placebo for all of the studies contributing to the analysis is 1.9 which is of nominal statistical significance." AdCom Tr. at 285-286, Slide 49.</p>	<p>"The overall odds ratio (CI) for the incidence of suicidality: 20 mg versus placebo for the cases indicated above was 1.9 (1.1, 3.1)." FDA Brief, <u>Clinical Review of Safety and Efficacy: Division of Metabolism and Endocrinology</u>, at 28, Fig. 4.</p>
<p>"[L]ooking just at the 7 obesity studies ... [y]ou can see our [odds ratio] has changed very little, still 1.8." AdCom Tr. at 286, Slide 50.</p>	<p>"When limited to the 7 obesity studies, the odds ratio for incidence of suicidality: 20 mg versus placebo was 1.8 (0.8, 3.8)." FDA Brief, <u>Clinical Review of Safety and Efficacy: Division of Metabolism and Endocrinology</u>, at 28, Fig. 5.</p>
<p>"I should point out that sensitivity analysis, adding the second randomization events to the first randomization, resulted in an exact te[s]t odds ratio of 1.93." AdCom Tr. at 286.</p>	<p>"For sensitivity analysis, the 2nd randomization events were added to the 1st randomization. The exact test OR [95% CL] was 1.93 [0.92, 4.28]. The p value was 0.11." FDA Brief, <u>Statistical Review of Safety: Division of Biometrics II</u>, at 12.</p>
<p>"Or is the association [between rimonabant and suicidality] causal? And we strongly believe that it is causal... So, in summary, our meta-analysis indicates an increased risk for suicidality, specifically suicidal ideation, in subjects taking rimonabant 20 mg versus placebo." AdCom Tr. at 292, Slide 59.</p>	<p>"Compared to placebo, 20 mg rimonabant statistically significantly increased suicidality based on analyses both of incidence rates and person-years." FDA Brief, <u>Statistical Review of Safety: Division of Biometrics II</u>, at 8.</p>

53. In short, the information that was publicly disseminated on June 13 about suicidality findings based on the Posner Codings was not new to the market. Rather, it was a repeat of information that had been publicly disclosed in the FDA Brief posted on June 11, 2007.

**b. The Market Did Learn a Great Deal on June 13 About the Views of the FDA Staff and the Advisory Committee, Including On Whether Rimonabant Should Be Approved, But Nothing That Was the Subject of an Alleged Misstatement**

54. What *did* make news on June 13 was how much weight the FDA staff attached to the previously-disclosed negative findings about rimonabant (not just suicidality but other adverse side effects) and the reaction of the AdCom to that information. But none of this was information that Defendants could have known (on February 24, 2006 when the FDA asked Sanofi to obtain an independent, formal assessment of the risk of suicidality, or on October 31, 2006 when the Posner Codings were submitted to the FDA).

**(1) The FDA for the First Time Publicly Disclosed Its Reactions and Opinions Regarding the Safety Data**

55. At the June 13, 2007 AdCom public hearing, representatives of the FDA, the Company and the public (including guest speaker Dr. Posner) spoke to the Advisory Committee. Presentations covered a host of topics, among them the Columbia University C-CASA Suicidality Assessment, rimonabant's mechanism of action, completed studies, medical need, clinical efficacy, clinical safety, and Sanofi's proposed risk management plan.<sup>45</sup> Only some of these topics related to suicidality.

56. The concluding presentation before the Committee's deliberations and voting was that of the FDA's Dr. Amy Egan, who discussed the clinical efficacy and safety of rimonabant. Her remarks were not limited to suicidality, but also encompassed other adverse events and methodological issues. Dr. Egan's presentation was distinguished from those earlier in the program by its repeated opinions expressing concern. Her concluding remarks are illustrative: "The potential market for this drug and our continued uncertainty about its risks, both known and unknown, lead to our concern about the use of this drug in the general population." A minute-

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<sup>45</sup> See Draft Agenda, FDA, FDA Center for Drug Evaluation and Research, Endocrinologic and Metabolic Drugs Advisory Committee Meeting, June 13, 2007, available at <http://www.fda.gov/ohrms/dockets/ac/07/agenda/2007-4306a-agenda-draft.pdf>; see generally AdCom Tr.

by-minute chart of Sanofi's volume-weighted average ADS price on June 13 reveals that the market's valuation of this security began to fall sharply around 2:30 p.m., shortly after Dr. Egan concluded her formal remarks. See Exhibit 3.b and 4.<sup>46</sup>

57. The FDA's Dr. Egan was not the only presenter on June 13 to address suicidality. Sanofi's Dr. Paul Chew, who presented in the morning on the clinical safety of rimonabant, did so as well, albeit without the sort of alarming language later used by Dr. Egan. Dr. Chew observed that there was an approximately "2-fold imbalance" in the incidence of "suicidal ideation" (i.e., "thoughts of wanting to be dead, wanting to die or ending one's life"), but that "there does not appear to be a signal" as regards "possible suicidal events." He also noted that "all of these cases were associated with a concomitant depressive disorder or adjustment disorder as Dr. Posner has indicated today. These did not occur as isolated events."<sup>47</sup> Dr. Chew said that in light of these results "[Sanofi] will recommend not treating patients with a history of depression or suicidality, not treating patients with an active diagnosis of depressive disorders or current antidepressant therapy."<sup>48</sup> Sanofi's ADS price was essentially flat throughout the morning of June 13. See Exhibit 3.b.

## (2) The AdCom Panel Unanimously Voted Not to Approve Rimonabant until the Drug Was Better Understood

58. The AdCom panelists were asked to vote on two questions: whether the available safety data were adequate at that time, and whether they would recommend rimonabant for approval. Prior to voting aloud on each question, each panelist was asked to discuss his or her "level of concern regarding rimonabant and psychiatric adverse events, in particular depression and suicidality, and neurological adverse events, in particular seizures, and the reasons behind

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<sup>46</sup> I present graphs of intraday ADS prices covering the period June 11 through June 14 not in lieu of daily event studies, which I introduce below, but rather to provide a visual representation of how prices moved in relation to news that was disseminated in the midst of a trading session. Notably, while Sanofi's ADS price dropped sharply upon the disclosure of negative FDA and AdCom Panel opinions on the afternoon of June 13, it did not visibly react on June 11 following the mid-morning release of the scientific findings that would prompt those opinions. See Exhibits 3.a and 3.b.

<sup>47</sup> AdCom Tr. at 112-113, 24.

<sup>48</sup> AdCom Tr. at 108.

[their] thinking on these issues.”<sup>49</sup> The transcript establishes that the panelists raised many issues, including: high attrition rates from clinical trials, small size of the study population compared to the much larger user population, unconvincing evidence regarding the drug’s effect on co-morbidities, elevated occurrence of anxiety and seizures, higher incidence of psychiatric side effects in general, quality of the safety data (including the lack of long-term data), patient’s quality of life, weight loss not sustained after drug discontinuation, and suicidality risk. See Exhibit 5.

59. While Dr. Egan’s expressions of concern about the FDA’s suicidality findings and other negatives augured poorly for rimonabant’s near-term prospects, they did not necessarily squash those prospects. The AdCom’s unanimous negative vote essentially did that, effectively putting to a halt the drug’s chances of approval.<sup>50</sup> Following that vote, analysts no longer believed the drug would win approval. The ADS price reflects this double-whammy of bad news, with the security taking a second tumble during and shortly following the vote. See Exhibit 3.b.

### **C. Choice of a Market Model for Sanofi ADS and a Market Model for the Ordinary Shares**

60. Having determined the true date of the corrective disclosure in this matter, I proceed to the next step in my event study: selection of a market model. I focus my remarks on the selection of such a model for the ADS, as that is the security principally at issue in this litigation, but comment as well on the comparable exercise that I undertook for the ordinary shares.

61. I estimated a series of theoretically sound market models before selecting one for my event studies in this case. Each estimated model relates Sanofi ADS’s daily logarithmic

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<sup>49</sup> See also AdCom Tr. at 329; FDA, Summary Minutes of the Endocrinologic and Metabolic Drugs Advisory Committee meeting on June 13, 2007, available at <http://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4306m1-final.pdf>.

<sup>50</sup> The FDA is not obliged to follow the recommendation of an Advisory Committee panel but it generally does so when that recommendation is negative. See Societe Generale, Rating downgrade FDA panel voted against the approval of rimonabant in the US by 14-0, June 14, 2007 (“The Endocrinologic and Metabolic Drugs Advisory Committee unanimously (14-0) voted against FDA approval for rimonabant in the US, saying that the 13,000 patient-rich clinical programme had not been large enough to properly characterise the safety profile of the drug. They also did not feel confident about the side-effect profile. As a consequence, panel members voted a negative

(“LN”) return to the daily LN return of a broad market index of US stocks or ADRs (four candidates) and/or a healthcare or pharmaceutical industry index (five candidates).

62. I estimated the models with daily returns data for February 25, 2006 through June 8, 2007, excluding October 31, 2006. This time frame coincides with the purported class period (February 20, 2006 through June 13, 2007), trimmed on each end to exclude days before the first challenged statement (February 24, 2006) and after the sole corrective disclosure (June 11, 2007), and further trimmed to exclude days with a challenged statement (February 24, 2006 and October 31, 2006) or (properly identified) disclosure (June 11, 2007). The resulting estimation period is long enough to reveal the ADS’s characteristic trading patterns with regard to the indices, and close enough to the events of interest as to provide a solid basis for opining on the ADS’s abnormal movements following each of them.

63. I decided in advance to base my event studies on the model that, subject to two restrictions, was best able to explain the ADS’ daily returns during the estimation period after controlling for the number of independent variables it employed, i.e., the model with highest “adjusted R<sup>2</sup>”.<sup>51</sup> One restriction was that none of the independent variables carry an illogical sign (i.e., behave “perversely”); the other was that none be indices in which Sanofi ADS was a component.<sup>52</sup>

64. The results of my ADS market model estimations are reported in **Exhibit 6**. When tested one at a time, in Models 1 – 9, each independent variable is a statistically significant predictor of Sanofi ADS’s daily returns. The NYSE Healthcare Index Excluding Sanofi (Model 6) is the best-performing index over all and performs in the industry sub-group. The S&P ADR

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recommendation to the FDA for its decision on 26 July. Usually, the FDA does not necessarily follow its panels’ decisions when they are positive, but follows them almost 100% when they are negative.”).

<sup>51</sup> Adjusted R<sup>2</sup> statistic measures the percent of variance in the dependent variable that is explained by the independent variables after adjusting for the number of independent variables relative to the number of observations. While R-squared always increases, or technically will never decrease, when a variable is added to the model, regardless of its explanatory power, adjusted R<sup>2</sup> only increases if the variable has explanatory power above some threshold.

<sup>52</sup> Sanofi ADS was a component of the NYSE Composite Index, the NYSE ARCA International Market Index, the S&P ADR Index, the NYSE ARCA Pharmaceutical Index, and the NYSE Healthcare Index during the estimation period. Using component weight data from Bloomberg, I was able to remove Sanofi from all but the S&P ADR Index. I do not have information on whether Sanofi is a component of the Nasdaq HealthCare Index.

Index (Model 4) is the best-performing broad market index, though it is somewhat advantaged by its inclusion of Sanofi.

65. Models 10 – 13 test two independent variables at a time: the best-performing industry index, NYSE Healthcare Index Excluding Sanofi, coupled with one or another of the four broad market indices. Each two-variable model outperforms the best one-variable model, as indicated by the higher adjusted  $R^2$ s in this set. Model 10 is the single-best predictor of Sanofi's ADS returns, with an adjusted  $R^2$  of 36.5%. Because it employs an industry index that includes Sanofi's ADS, however, which biases results in its favor, I reject it in favor of Model 12, the next-best performer, whose broad market index is the NYSE ARCA International Market Index Excluding SNY.<sup>53</sup> Model 12 has an adjusted  $R^2$  of 35.13% and both of its independent variables are statistically significant at the 5% level. It is this model that I rely on for my ADS event studies.

66. I report my ordinary shares market model estimations in **Exhibit 7**. In all seven models, each independent variable is a statistically significant predictor of Sanofi ordinary shares' daily returns. The FTSE Eurotop 100 Index Excluding Sanofi (Model 2) and the Bloomberg Europe 500 Pharmaceuticals Index Excluding Sanofi (Model 4) are the best-performing indices in the broad market and industry groups, respectively. Model 7, which tests these independent variables together, is what I rely on for my ordinary shares event studies as it has the highest adjusted  $R^2$  (35.70%) and both of its independent variables are statistically significant at the 5% level.

#### **D. The June 11, 2007 Corrective Disclosure Was Not Followed by a Statistically Significant Drop in the Price of Sanofi ADS or Ordinary Shares**

67. From the close of trading on Friday, June 8, 2007 to the close on Monday, June 11, 2007, the price of Sanofi ADS fell by \$0.36, from \$45.50 to \$45.14. Because the predicted ADS return on the 11<sup>th</sup> is slightly positive, the abnormal price change (calculated using Model 12) is slightly more negative: a drop of \$0.43 or 0.9%. Even so, the one-day move does not

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<sup>53</sup> I could not obtain and remove Sanofi ADS's contribution to the S&P ADR Index. Because the returns of any index that includes a stock depend on that stock's returns—a circumstance that mathematically works to strengthen the association between the stock return and the index return—the adjusted  $R^2$ s of Models 10 and 11 are upwardly biased.

begin to approach statistical significance at the 5% level.<sup>54</sup> Whereas a t-statistic of 1.97 in absolute value would have been required for significance at that level, here the t-statistic is just 0.89 in absolute value.<sup>55</sup> See **Exhibit 8.c**.

68. That Sanofi's ADS price did not significantly fall following disclosure of the information alleged to have been improperly omitted means that **the omitted information was not material**.<sup>56</sup> This conclusion is particularly solid because the information entering the market on June 11 was not simply what was credibly alleged to have been omitted (i.e., that the FDA had asked Sanofi to obtain certain data, and that Sanofi did so and provided those data to the FDA), but negative news that (despite allegations to the contrary) was in fact timely disclosed (i.e., the FDA staff's finding of a significant relationship between rimonabant and suicidality). If Sanofi's price *had* significantly fallen on June 11, it would have been impossible to conclude from this that the omitted information *was* material, as potentially (and more

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<sup>54</sup> Throughout this report, unless otherwise noted, when I use the term "statistically significant" in connection with event study findings, I am referring to results that are so at the 5% level. This is the commonly accepted level of statistical significance in the social sciences. The United States Supreme Court has endorsed a rule of two or three standard deviations, which corresponds to statistical significance at approximately the five percent level (for two standard deviations) or stronger (for three standard deviations). See Castaneda v. Partida, 430 U.S. 482 (1977), fn. 17 ("As a general rule for such large samples, if the difference between the expected value and the observed number is greater than two or three standard deviations [sic], then the hypothesis that the jury drawing was random would be suspect to a social scientist."). Similarly, in Goldkrantz v. Griffin, No. 97 Civ. 9075 (DLC), 1999 WL 191540, at \*14 (S.D.N.Y. Apr. 6, 1999), aff'd 201 F.3d 431 (2d Cir. 1999), the court rejected an attempt to use a standard less stringent than the 5% significance level (also known as the 95% confidence level) for an event study in that securities case. ("Plaintiff has, however, provided no explanation for why a 95% confidence interval is inappropriate, other than its failure to pick up the 2.64% price change.") Additionally, p. 251 of the Federal Judicial Center's 2011 *Reference Guide on Statistics* states, "In practice, statistical analysts typically use levels of 5% and 1%. The 5% level is the most common in social science, and an analyst who speaks of significant results without specifying the threshold probably is using this figure." In the In re AIG Securities Litigation, 265 F.R.D. 157 (S.D.N.Y. 2010) at fn. 28, the Court stated, "This does not demonstrate, however, that it is consistent with standard methodology in financial economics, or in conducting event studies specifically, to draw conclusions at the 10% level." In Moody's, 274 F.R.D. at 489, this Court, citing the AIG decision, stated, "[a negative return at the 90% confidence level] is below the conventional statistical measure of a 95% confidence level and therefore is not sufficient evidence of a link between the corrective disclosure and the price."

<sup>55</sup> The June 11 abnormal ADS price change is not statistically significant even at the less stringent 10% level; I note this even though, as explained above, supra n. 54, I do not believe 10% to be the appropriate standard for measuring statistical significance in event studies. Likewise, even though I do not believe an event window of more than one day to be appropriate when, as here, the one-day move is statistically insignificant, supra n. 33, I note that a two-day (June 11 and 12) window also fails to produce a cumulatively significant drop in ADS price, notwithstanding an abnormal price drop on each day individually; the t-statistic on two-day cumulative abnormal return is only .94. See **Exhibit 8.c**.

<sup>56</sup> More precisely, **plaintiffs will be unable to prove that the omitted information was material**. The burden of proof is on Plaintiffs to establish materiality; the event study shows that they will not be able to meet that burden.

reasonably) any drop would have been due to the new medical findings, not the data request and delivery.

69. Given the critical importance of my June 11 event study result to the question now before the Court (i.e., materiality), I decided to assess whether the result was sensitive to my choice of market model. Towards that end, I repeated the analysis of **Exhibit 8.c** using each of the other 12 market models in **Exhibit 6**. None of the 13 models yields a significant negative abnormal return on June 11. All yield a negative abnormal return (ranging from -0.75% to -1.26%, or -\$0.34 to -\$0.57), but the associated t-statistics are in every case statistically unremarkable (ranging in absolute value from 0.66 to 1.14). See Exhibit 10.

70. My conclusion that the omitted information was not material is robust to market model specification.

71. This conclusion is also robust to choice of security. By conducting an event study for Sanofi ordinary shares on June 11, 2007, I determined that the French market was as unmoved by the corrective information as the US market.

72. From the close of trading on Friday, June 8, 2007 to the close on Monday, June 11, 2007, the price of Sanofi ordinary shares fell by €0.05, from €67.57 to €67.52. Because the predicted ordinary shares return on the 11<sup>th</sup> is positive, the abnormal price change (calculated using Model 7) is more negative: a drop of €0.66 or 1.0%. The move in the ordinary shares does not begin to approach statistical significance at the 5% level (or indeed at the 10% level) on June 11, June 12 (which I consider because the news of the FDA Brief was posted late in the June 11 trading session in Europe), or over the two days cumulatively. See Exhibit 9.c. This finding holds for all seven market models. See Exhibit 11.

### **E. The Events of June 13, 2007 Were Followed by a Statistically Significant Drop in the Price of Sanofi ADS or Ordinary Shares**

73. While the June 13 news does not reveal anything that Defendants knew or could have known on February 24, 2006 or October 31, 2006, as shown above, I conducted an event study to assess price movement following that news. I find a statistically significant ADS price drop on both June 13<sup>th</sup> and June 14<sup>th</sup> and no significant move on June 15<sup>th</sup>. Adjusted for market and industry, the two-day abnormal drop cumulates to 8.4% or \$3.71 and is significant at the 5%

level.<sup>57</sup> See **Exhibit 8.d**. Notwithstanding its statistical significance, this price movement has no bearing on the materiality question now before this Court because, as explained above, the information alleged to have been omitted was fully revealed previously, on June 11, 2007. What moved the ADS on June 13<sup>th</sup> and June 14<sup>th</sup> is not allegation-relevant.

74. My event study for the ordinary shares on June 14, 2007 (the first day when Euronext Paris would have been able to register a reaction to the FDA opinions and AdCom vote, which occurred on June 13<sup>th</sup> after trading in Europe had closed) finds a statistically significant abnormal drop there as well.

## **VI. EVENT STUDY EVIDENCE FOR THE CHALLENGED STATEMENTS ALSO ARGUES AGAINST CLASS CERTIFICATION**

75. In its Moody's class certification opinion, this Court wrote: "To a proper confidence level ... there is no date on which any alleged misrepresentation caused a statistically significant increase in the price. In other words, Defendants have severed the link between the misrepresentation and the price by showing that the allegedly false information the market was absorbing was not causing the stock price to artificially inflate."<sup>58</sup> In light of the importance that the Court attaches to such findings, I conducted an event study for each challenged statement to learn how the ADS price behaved immediately thereafter.<sup>59</sup> As I describe below, neither challenged statement was followed by a statistically significant ADS price increase.

76. I first tested how the ADS price behaved on February 24, 2006, the day of the first challenged statement. From a \$42.69 close the prior day (February 23) to its \$43.22 close on the event day, the ADS rose by \$0.53. Because the predicted return is slightly negative, the

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<sup>57</sup> A two-day event window (or equivalently, back-to-back one-day event windows) is called for in this instance because the June 13 vote was not concluded until 4:08 p.m. ET and therefore could not be priced during regular trading hours until the next day.

<sup>58</sup> See Moody's, 274 F.R.D. at 493.

<sup>59</sup> Whether a security's failure to significantly rise in price following an alleged misrepresentation implies that the information was not material depends upon how the allegedly false information affects expectations. If misinformation makes beliefs and expectations rosier than they had been, then certainly price should rise if the misinformation is material. If misinformation merely maintains prior expectations, however, whereas truthful information would be disappointing vis-à-vis expectations, then one would not expect the misinformation to move price. Rather, it might impart inflation by averting a stock price fall that would otherwise have happened. The challenged statements in the present case are of the latter variety. Rather than falsely enhancing the perceived prospects for rimonabant's approval vis-à-vis market expectations, Defendants are alleged to have omitted facts that, if disclosed, allegedly would have caused perceived prospects to deteriorate. See FAC ¶105.

abnormal price change (calculated using Model 12) is slightly more positive: a rise of \$0.57 or 1.3%. With a t-statistic of just 1.24, however, the move is not even close to statistical significance at the 5% level. See Exhibit 8.a. A finding of no statistically significant price increase holds under all 13 of my market models. See Exhibit 10.

77. Similarly, I conducted an event study for October 31, 2006, the date of the second challenged statement. Sanofi's ADS price fell by \$0.81: to \$42.69 that day from a close of \$43.50 the day before. Adjusted for prediction, which was slightly negative based on market and industry movements, the abnormal ADS price drop was \$0.70 or 1.6%. Along with being statistically insignificant (the associated t-statistic is 1.54), the abnormal move is not in the same direction as a materiality showing would require (i.e., it is negative, not positive). See Exhibit 8.b. Similar findings-- i.e., a statistically insignificant move in the "wrong" direction—hold for all 13 market models. See Exhibit 10. I do find a statistically significant move in the ordinary shares on October 31, 2006 with all seven models but it is negative, and therefore does not constitute evidence that the day's alleged *positive* misinformation was material.

78. I conclude that Plaintiffs will not be able to establish materiality with stock price evidence relating to the alleged misrepresentations any more than they can expect to do with stock price evidence relating to the true disclosure date, June 11, 2007.<sup>60</sup> No matter which of 13 reasonable market models is used, *no* allegation-relevant date has associated with it the sort of ADS price behavior that might allow Plaintiffs to withstand a challenge to their materiality assertion or to deflect efforts to rebut a presumption of reliance.

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<sup>60</sup> On both alleged misrepresentation days, in addition to commenting on rimonabant's status, the Company reported financial results and issued guidance. To properly assess the impact of the challenged statements, one would need to determine the price impact of the unrelated news, which on both dates was mixed vis-à-vis expectations. (1) On February 24, 2006, when 4Q05 was announced, net profit beat analysts' estimates but operating income fell short. The Company also issued its first guidance for FY06: 10% EPS growth compared to 26% in FY05, citing declining Plavix sales from generic competition and an uncertain global outlook as reasons for the projected slowdown. (2) On October 31, 2006, when 3Q06 was announced, net profit again was high relative to consensus but now revenues fell short. Further complicating the picture, the Company slightly raised its full- year guidance from 2% EPS growth to "at least 2%," but even the latter could have put it well below consensus. For more details see **Exhibits 8.a** and **8.b**. To establish materiality for the challenged statements when made using price evidence, Plaintiffs would have to show that price rose significantly after accounting for all confounding news. They have not done so.

## **VII. OTHER EVIDENCE BUTTRESSES THE EVENT STUDY FINDINGS, FURTHER ERODING PLAINTIFFS' CLAIMS TO MATERIALITY AND RELIANCE**

### **A. The Market Knew Before June 11, 2007 that Rimonabant Had Adverse Psychiatric Side Effects and Might Be Causally Linked to Suicidality**

79. Because legal notions of materiality may not perfectly correspond to economic notions, I also examined non-price evidence with respect to materiality. Such evidence, which goes to market knowledge, can be obtained by a review of analyst reports.

#### **i. Many Analysts Commented Before June 11 on a Potential Link Between Rimonabant and Suicidality**

80. To learn whether the market was aware before release of the FDA Brief that rimonabant might pose a risk of suicidality, I systematically reviewed a sample of Sanofi-specific English-language analyst reports issued from January 1, 2006 through June 10, 2007.

81. Over the slightly longer period January 1, 2006 through June 30, 2007, Sanofi was followed by at least 38 analyst research firms that together issued at least 815 English-language, non-technical reports focused on the Company.<sup>61</sup> To obtain and review all of these would have been prohibitively expensive. Instead, I conducted an electronic keyword search for words beginning with "suicid" on the approximately 2,285 reports that were already in my possession.<sup>62</sup>

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<sup>61</sup> My team estimated the minimum number of analyst reports that focused on, and securities firms that followed, Sanofi over the specified period using three datasets. (1) Initially, we received a set of analyst reports from counsel. It is our understanding that these represented all reports that Sanofi had readily available at the time the set was compiled (approximately fall of 2010). On or about October 3, 2011 we conducted an independent search for all reports that could be purchased from (2) Thomson Investext or (3) Reuters Knowledge. Cross-referencing the three sources we prepared a list of unique analyst reports published by these firms during the review period. In the event of mergers between list members, we count only the new entity. See Appendix 3. In addition, approximately 1,470 reports were produced in this litigation before March 19, 2012 pursuant to subpoenas from Plaintiffs and Defendants by the following analysts: Cowen & Co., Exane BNP Paribas, Goldman Sachs, Morgan Stanley, Prudential Equity Group, Raymond James, Societe Generale, and UBS Investment Research. From these production reports, we identified approximately 289 English-language, non-technical, Sanofi-specific reports issued from January 1, 2006 through June 30, 2007. We did not add any of these 289 reports to the 815 but some may have been in that group. If none were, the number of unique analyst reports issued during the period would be  $815 + 289 = 1,104$ .

<sup>62</sup> The analyst reports that I searched for this and other analyses figuring in this Declaration are those in my possession (which may include duplicates, industry reports, reports not in English, reports on other companies, and reports from outside the period January 1, 2006 through June 30, 2007), consisting of: (a) the initial set of analyst reports provided to me by counsel; (b) additional reports known to have been published in the 5 calendar days beginning with a challenged statement or the corrective disclosure (i.e., February 24-28, 2006, October 31-November 4, 2006, and June 11-June 17, 2007); (c) additional reports sufficient to ensure that we had at least one

82. Plaintiffs claim that the market was not aware prior to June 13 of the risk that rimonabant caused suicidality. That claim is false. The results of my electronic search are detailed in **Exhibit 12**. At least 10 analysts had suicidality on their radar at some point during the 17-month-and-10-day period prior to June 11, and four did so before February 24, 2006. These four analysts (and the broader market that they represented) presumably would not have been surprised to learn on February 24, 2006 that the FDA's unwillingness to approve rimonabant at that time (something they had known for a week) would have stemmed in part from the FDA's interest in obtaining more information on the drug's possible link to suicidality. Likewise, they presumably would not have been particularly surprised to learn on October 31, 2006 that Sanofi's submission to the FDA in response to the approvable letter included data pertaining to suicidality.

83. Below are examples of analyst commentary reflecting an awareness of suicidality risk even before the start of the Class Period:

- “In addition, we highlight that the FDA may be more cautious in its view of Acomplia following the issue of suicidal tendency in adolescents with certain marketed anti-depressants (e.g. GSK's Paxil), which surfaced last year.

...

**Key concern – potential for unknown outliers with severe reaction**

However, our key concern at present is that there is no detailed published data on the stratification for the severity of depression occurring i.e. to answer the question of whether there is a small (but significant) subset of patients that experience severe depression / suicidal tendency with Acomplia therapy. Although the company and lead investigators of the studies do not believe these CNS issues to be of significant concern, the FDA may take a more cautious view.” Merrill Lynch, Revisiting Acomplia, January 31, 2006 (emphasis added).
- “On Wednesday, Sanofi announced that the European Commission has granted marketing authorization in all 25 European member states for Acomplia (Zimulti, rimonabant) . . . . The Acomplia wording for patients with uncontrolled serious psychiatric illnesses is no surprise given Acomplia's CNS activity. The limitation does not seem to rule out use in patients with controlled serious psychiatric illnesses.

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report (if extant) by each of the 38 analysts from each of 1H2006, 2H2006, and 1H 2007 (but before June 11, 2007); (d) additional reports sufficient to ensure that for each analyst for whom we had a report issued from June 11 through June 17, 2007, we had that analyst's last report published prior to June 11, 2007; and (e) the approximately 1,470 reports that were produced in this litigation pursuant to subpoenas from Plaintiffs and Defendants before March 19, 2012 by the following analysts: Cowen & Co., Exane BNP Paribas, Goldman Sachs, Morgan Stanley, Prudential Equity Group, Raymond James, Societe Generale, and UBS Investment Research. Reports that were not obtained from counsel were purchased via Thomson Investext or Reuters Knowledge.

As such, we do not see the limit as a major obstacle: **After all, common sense dictates a patient with a serious psychiatric illness, e.g. who has psychosis or suicidal thoughts, should not be put on Acomplia first but should be treated and controlled prior to starting Acomplia or a great number of other therapies.**

Bernstein Research, Sanofi-Aventis: Acomplia Approved in E.U.; U.K. Launch in July; Certainty a Plus for Sentiment and Potentially Revisions, June 22, 2006 (emphasis added).

- “As for Acomplia, we attribute much of the recent weakness in its shares to uncertainty ahead of Acomplia’s PDUFA. **Based on the side profile (including suicide rate)** seen in the 300,000 European patients prescribed Acomplia since its 3Q/06 European launch, we remain comfortable with Acomplia’s safety profile. **Despite a conservative and increasingly unpredictable FDA** (evident by the recent Galvus delay), **we continue to anticipate a US approval for Acomplia in July.**” Bank of America, Favorable Risk/Reward; Mgmt Meetings Highlight Pipeline Opps, March, 16, 2007 (emphasis added).
- “If Zimulti does not get through this time, its next chance is 2012... **Side effects predicted in our 8th February [2006] report "Mission Acomplia I" now seen in humans: Memory loss, convulsion and hallucinations along with a case of suicide in unclear circumstances.** Combining this with only modest weight loss, some weight regain despite continuous use, the long term risk-benefit makes us **err on the side of caution going into the panel.**” Citigroup, Acomplia[']s Judgment Day, June 8, 2007 (emphasis added).

84. Analysts’ prior awareness of rimonabant’s potential link to suicidality is a credible explanation for the ADS’s failure to significantly decline on June 11 following news of the FDA’s finding of a statistically significant link.

#### **ii. Four Published RIO Trials Reported a Higher Incidence of Depression and Psychiatric Adverse Events in Patients Taking Rimonabant**

85. The results of Sanofi’s four Rimonabant in Obesity (“RIO”) clinical trials were published in medical journals from April 16, 2005 through November 11, 2006. All of these study reports were available to the market. Though they did not report suicidality as a side effect, the articles reported on the incidence of depression and psychiatric disorders. Notably three of the RIO trials were reported on *before* the first challenged statement. All four RIO studies reported depression/psychiatric disorders as the most common adverse event leading to withdrawal from the trial, and two of the studies (RIO-Europe and RIO-North America) reported a higher incidence of depression/psychiatric disorders in patients taking rimonabant:

- “The frequency of adverse events was slightly higher in the rimonabant 20 mg group than in the rimonabant 5 mg and placebo groups ... **The most common adverse events leading to study discontinuation were depressed mood disorders in all treatment groups**; discontinuations due to nausea, vomiting, diarrhoea, headache, dizziness, and anxiety were more frequent in the rimonabant 20 mg group than in the other groups (table 7) ... Serious adverse events did not seem to occur more frequently in the patients treated with rimonabant than in those on placebo. **Mood disorders were more frequent in the rimonabant 20 mg treatment group than in the other groups** [Table 6 reports “psychiatric disorders” as serious adverse event in **1.5% of patients on rimonabant 20 mg vs. 0.3% on placebo**], but the discontinuation rate due to this adverse event was similar between rimonabant 20 mg and placebo in this study.” Luc F. Van Gaal, Aila M. Rissanen, André J. Scheen, Olivier Ziegler, & Stephan Rössner, Effects of the cannabinoid-1 receptor blocker rimonabant on weight reduction and cardiovascular risk factors in overweight patients: 1-year experience from the RIO-Europe study, The Lancet, Vol. 365, Apr. 16, 2005, at 1393-94, 1396 (emphasis added).
- “**The most frequent adverse events resulting in discontinuation in the groups receiving rimonabant at 5 mg and 20 mg, as compared with placebo, included depression (1.7 percent and 2.9 percent, respectively, vs. 0.6 percent)** ... The adverse-event profile of rimonabant observed in the RIO-Lipids study was found to be concordant with the results of the RIO-Europe study.” Jean-Pierre Després, Alain Golay, & Lars Sjöström, Effects of Rimonabant on Metabolic Risk Factors in Overweight Patients with Dyslipidemia, The New England Journal of Medicine, Vol. 353, No. 20, Nov. 17, 2005, at 2130-2131, 2133 (emphasis added).
- “Compared with patients receiving placebo, **the overall incidence of adverse events leading to [RIO-North America] study withdrawal in year 1 was slightly higher in patients receiving 5 mg of rimonabant and even greater in patients receiving 20 mg of rimonabant, mainly due to psychiatric, nervous system, and gastrointestinal tract adverse events**. Compared with patients receiving placebo, **adverse events** (upper respiratory tract infection, nasopharyngitis, nausea, influenza, diarrhea, arthralgia, anxiety, insomnia, viral gastroenteritis, dizziness, **depressed mood**, and fatigue) **were reported in 5% or greater of patients receiving 20 mg of rimonabant.**” F. Xavier Pi-Sunyer, Louis J. Aronne, Hassan M. Heshmati, Jeanne Devin, & Julio Rosenstock, Effect of Rimonabant, a Cannabinoid-1 Receptor Blocker, on Weight and Cardiometabolic Risk Factors in Overweight or Obese Patients, J. Am. Med. Ass’n., Vol. 295, No. 7, Feb. 15, 2006, at 772 (emphasis added).
- “**The incidence of adverse events that led to discontinuation was slightly greater in the 20 mg/day rimonabant group, mainly due to depressed mood disorders, nausea, and dizziness (table 4).** However, no serious adverse events linked to psychiatric disorders were recorded in either rimonabant group. ... Rimonabant was well tolerated in this study, with adverse events that were generally transient and mild, and much the same as the safety profile reported in non-diabetic patients. **The most frequent adverse event that led to premature withdrawal in the 20 mg/day**

**rimonabant group was the occurrence of self-reported depression. However, objective measures of depression and anxiety from the HAD scales showed only slight and probably not clinically relevant changes in the 20 mg/day rimonabant group compared with the placebo group. Nevertheless, in this [RIO-Diabetes] trial, as in other RIO-trials, patients with severe psychiatric disorders or receiving antidepressants were excluded, so the safety of rimonabant in such individuals remains to be determined.”** André J. Scheen, Nick Finan, Priscilla Hollander, Michael D. Jensen, & Luc F Van Gaal, Efficacy and Tolerability of Rimonabant in Overweight or Obese Patients With Type 2 Diabetes: A Randomized Controlled Study, *The Lancet*, Vol. 368, Nov. 11, 2006, at 1660, 1670 (emphasis added).

An editorial that accompanied publication of the RIO-Diabetes study noted with concern the suggested causal relationship between rimonabant and psychological distress:

“The links between obesity, diabetes, and psychological distress (often in a context of social and economic deprivation) are well known and represent a vicious cycle that is difficult to break. ... **In this context, the suggestion that rimonabant increases depression and anxiety is concerning.** Although the authors of RIO-Diabetes propose that average change in the depression and anxiety score is unlikely to be clinically meaningful, the study recruits had relatively low scores, perhaps somewhat lower than scores generally characteristic of a population with type 2 diabetes. By contrast, reported levels of self-esteem and health-related quality of life significantly improved with active treatment in RIO-Diabetes, presumably as a result of successful weight loss. Clearly, further work needs to be done to disentangle and clarify these mixed messages. In the meantime, psychological morbidity should be formally assessed before consideration of this pharmacological approach.” Stephen J. Cleland & Naveed Sattar, Does rimonabant pull its weight for type 2 diabetes?, *The Lancet*, Vol. 368, Nov. 11, 2006, 1632, 1634 (emphasis added).

### **iii. Most Analysts Were Cognizant of Rimonabant’s CNS and Depression-Related Side Effects Before June 11**

86. While many Sanofi analysts explicitly referenced suicidality prior to June 11, 2007, still more wrote about awareness of rimonabant’s association with depression, psychiatric, and CNS issues. For that broader group as well the June 11 statistical findings might not have come as a surprise. Indeed, a UBS analyst articulated the connection: “We continue to believe that the higher incidence of *depression* associated with Acomplia, *leading to* a possible increase in the risk of *suicidal behaviour*, may pose a potential hurdle to approval.” UBS, Risk, but what return?, Feb. 14, 2007 (emphasis added).

87. To gauge analyst awareness of rimonabant's psychiatric risks generally, I conducted an electronic keyword search on the same set of analyst reports examined above, now for the terms "psychiatric," "CNS," "central nervous system," or "depress." This produced many more hits than the search for "suicid." Sixty-six percent of analyst firms (25 of 38) published at least one Sanofi-specific report mentioning rimonabant's depression, psychiatric or CNS side effects during the review period (January 1, 2006 through June 10, 2007). Every firm that mentioned suicidality also turned up in this search. See Exhibit 13.

88. The market was acutely aware of rimonabant's psychiatric, CNS, and depression-related side effects, including a possible link to suicidality, before the FDA's findings of a statistically significant suicidality link were made public on June 11. It is reasonable to suppose that this prior knowledge may have rendered the FDA's findings immaterial to investors in their assessment of the drug's prospects. Even with such knowledge, it would not have been unreasonable for them to expect rimonabant to be approved by the FDA, albeit perhaps with a restrictive label. Rimonabant would not have been the first drug to be sold with FDA approval notwithstanding a known association with suicidality.<sup>63</sup>

**iv. Rimonabant's Suicidality, CNS and Depression-Related Side Effects Were Also Reported in News Before June 11**

89. During and prior to the class period, prior to the release of the FDA's findings, major news publications and financial press commented on Acomplia's depression and psychiatric side-effects. Here are a few examples from major publications:

- "Even with rimonabant, which has fewer side effects, the potential for trouble should not be ignored. The drug acts centrally, and could alter mental activity. 'It is impossible to predict what will happen with behaviour in the patient population at large. **Who knows if rimbonabant will increase the risk of mood disorders and suicide rates in vulnerable individuals, for instance,**' speculates [Shahrad Taheri,

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<sup>63</sup> See, e.g., Press Release, FDA, FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated With Antidepressant Medications, Oct. 15, 2004, available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108363.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108363.htm) ("In letters issued today, FDA directed the manufacturers of all antidepressant medications to add a 'black box' warning that describes the increased risk of suicidality in children and adolescents given antidepressant medications and notes what uses the drugs have been approved or not approved for in these patients. FDA's letters to the manufacturers also discuss other labeling changes designed to include additional information about pediatric studies of these drugs. **These labeling changes are applicable to the entire category of antidepressant medications because the currently available data are not adequate to exclude any single medication from the increased risk of suicidality.**") (emphasis added).

from the Henry Wellcome Laboratories for Integrated Neuroscience and Endocrinology in Bristol].

The ideal slimming drug remains elusive. In a Lancet commentary published in January 2007, researchers from the University of Alberta Hospital in Canada pointed out that each of the agents currently approved to treat obesity carry potentially serious adverse effects. They call for more long-term data to enable clinicians to assess whether patients should be using them or not.” Lisa Melton, Fat prophets/With over half the adult population in the developed world either overweight or obese, the search for lucrative fat-fighting drugs is gaining speed. Lisa Melton reports, Chemistry and Industry, Apr. 23, 2007 (emphasis added).

- “Clinical trials of Acomplia, whose generic name is rimonabant, revealed that a **few patients reported depression and anxiety, which is a reason some doctors have urged caution**. In a research paper, Goldman Sachs predicted that **because of those central nervous system side effects**, Acomplia would be approved only on the condition the company conducted a rigorous postmarketing surveillance program.” Stephanie Saul, Approval Delayed for Weight-Loss Drug, N. Y. Times, Feb. 18, 2006 (emphasis added).
- “There was **some evidence that study participants taking the drug may have shown higher rates of psychiatric side effects**. A listing of “adverse events” in the JAMA study showed a rate of 6.1% for anxiety among patients taking a 20 mg dose of rimonabant, and 2.1% for those on placebo. **Similarly, there was a 5.2% rate of “depressed mood” among those on the high rimonabant dose, but just 3.1% on placebo**. Those taking the drug also had a higher rate of nausea.” FDA Deals a Blow to Sanofi Weight-Loss Drug, Wall St. J., Feb. 18, 2006 (emphasis added).
- “Last week, the agency rejected Acomplia for people who want to quit smoking and asked Sanofi to conduct another study if it wanted to win approval for that use. The company said it planned to pursue that indication. ‘In the next few weeks, we’ll be meeting with the F.D.A.,’ Mr. Le Fur said. ‘We expect to introduce the drug this year.’ That’s most likely to happen in the second half, he added. **Acomplia has been linked to side effects including depression**. Mr. Dehecq repeated in a televised interview that he expected the drug to generate peak sales of about \$3 billion ‘but until we have the label nobody knows exactly.’” Anna Wilde Mathews & Ron Winslow, Sanofi to Pursue Approval of Weight-Loss Drug, N. Y. Times, Feb. 25, 2006 (emphasis added).
- “Still, Sanofi may need to jump some hurdles to win approval of rimonabant. **The FDA may be asking for more clarity on the drug’s novel and relatively untested mechanism, or on why patients taking rimonabant in one trial experienced a higher rate of psychiatric side effects, including depression and anxiety**, than those taking the placebo.” Jeanne Whalen, Sanofi Aims to Sell Obesity Drug This Year, Despite FDA Setback, Wall St. J., Feb. 25, 2006 (emphasis added).

- **“Among the side effects reported by patients taking Acomplia were nausea, depressed mood and skin tingling, which led to a discontinuation rate of 9.4%, compared with 2.1% in the placebo patients.”** Elena Berton, Sanofi Obesity Drug Helps Sugar Levels Of Diabetics in Study, Wall St. J., Dec. 6, 2006 (emphasis added).
- “Despite an ongoing delay in its debut, Acomplia holds promise. Already available in Europe, the Sanofi-Aventis (SNY) product not only helps patients lose weight, but improves cholesterol and blood-sugar levels, suggesting other possible uses. **Concerns have been raised about the possibility that the drug contributes to depression.** So, rather than approving Acomplia last February, the FDA requested additional data.” Johanna Bennet, Weekday Trader: Five Breakthrough Drugs for 2007, Barron’s Online, Jan. 15, 2007 (emphasis added).
- “Three years later, Acomplia is looking less like a miracle. The drug still hasn’t hit the market in the U.S. The Food and Drug Administration has asked for more data and repeatedly put off approval for the drug as an obesity treatment, while rejecting it for smoking cessation. **Side effects associated with Acomplia -- including depression and anxiety -- are likely giving the FDA particular cause for concern, analysts and doctors say. ... But there was a warning sign too: Patients on the 20-milligram dose had a 6.2% rate of psychiatric disorders such as depression, compared with 2.3% of those taking a placebo. ...** While the FDA and Sanofi decline to discuss the reasons for the delay, **outside specialists believe the sticking point likely has to do with the depression and anxiety side effects.** That’s especially an issue for a drug that some patients who are desperate to lose weight may seek out aggressively.” Jeanne Whalen, Slim Pickings: ‘Miracle’ Obesity Pill Looks Less Miraculous --- Repeated FDA Delays, European Restrictions Ail Sanofi’s Acomplia, Wall St. J., Mar. 29, 2007 (emphasis added).

## **B. Analysts Did Not View the FDA’s Suicidality Finding as Substantially Impairing the Drug’s Prospects for Approval**

90. FDA approval frequently entails a delicate balancing of risks in relation to benefits. If the market believed that the FDA’s likelihood of coming down on the side of approval was not substantially impaired by the newly disclosed scientific findings, failure of the ADS not to fall significantly on June 11 would make sense. Plaintiffs claim the suicidality findings meant that “Sanofi’s application to the FDA for rimonabant was now in extreme peril.”<sup>64</sup> I find, to the contrary, that even after these findings were made public on June 11, 2007, analysts did not expect non-approval.

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<sup>64</sup> FAC, ¶11.

91. In this inquiry, I compare the views of individual analysts about rimonabant's approval prospects across three periods: just prior to posting the FDA Brief; during the interim period (June 11 and 12) between that posting and the AdCom meeting; and in the days immediately following the AdCom meeting and vote.

92. First, to assess the impact on sentiment of the FDA Brief *per se* (of interest because that document contained all of the alleged corrective information), I compared the interim period view of each analyst who issued a report on either of those two days to that same individual's view in his or her last published pre-Brief (i.e., pre-June 11) report. Ten analysts commented on rimonabant in a report issued in the interim period. For six of the ten, I was able to assess the analyst's outlook for the drug in both the interim period and at the time of their last prior report. One of the six became less positive/more negative in outlook while the other five were unchanged. See Exhibit 14.

93. Along with examining outlook *change*, I studied what analysts who published a report in the interim period were then expecting. Nine of the ten who commented on rimonabant mentioned non-approval as a possibility but none wrote that non-approval or a panel vote recommending against approval was the likely outcome. The Citigroup analyst was arguably the most pessimistic but even he did not indicate during the interim period that he regarded non-approval as likely, predicting a split vote at best and a subsequent approvable letter. Seven of the ten raised the *possibility* of approval with a warning but made no firm prediction, only saying that it was a "close call," "difficult to tell," or that the panel would be mixed at best. The other three predicted approval with a warning about the possible risk of developing suicidality while taking the drug. The reasons that analysts issuing a prediction gave for their relatively optimistic assessment (i.e., restricted label approval) include manageable adverse side effects and a favorable risk/benefit profile. See Exhibit 14.

94. I supplemented my review of text commentary with an examination of rating changes during the two days following posting of the FDA Brief. *None* of the 11 analyst reports issued in this interim period reported a change in rating, which in seven instances was bullish (i.e., "Buy," "Add," or "Overweight"). See Exhibit 15.

95. The non-price evidence (before-after approval expectations and stock ratings) reinforces the previously reported price evidence (both the intraday charts and the event study

findings). All establish that the Brief, notwithstanding its statistically significant suicidality findings, did not cause analysts to materially lower their opinion of Sanofi's ADS or ordinary shares.

96. Second, I examined sentiment and ratings and changes in same in the wake of the June 13 AdCom vote.

97. **Exhibit 16** excerpts rimonabant commentary from all analyst reports published during the three days June 13 (post-vote) to June 15, 2007. Generally, analysts were surprised by the AdCom's unanimous (14-0) negative vote on whether to recommend rimonabant and pointed to inadequate safety data as the major reason for it.

98. **Exhibit 17** reports the interim period approval outlook and the post-vote approval outlook of each analyst who published at least one report on June 11 or June 12, and at least one on June 13 (after the AdCom vote) through June 15, 2007. Following the AdCom vote, all nine of these analysts changed their view about the most likely outcome for rimonabant from approval to non-approval. Four of the nine added that they were removing rimonabant sales from their forecasts.

99. I also examined rating changes in the wake of the AdCom vote among all (23) analysts who issued a report on June 13, June 14, or June 15. Among the subgroup of 10 whose last previous report came out during the interim period (i.e., after posting of the Brief), four (40%) downgraded the ordinary shares or the ADS; among the subgroup of 13 whose last previous report came out prior to the Brief, five (38%) downgraded. That the latter sub-group behaved nearly identically to the former and that a substantial fraction of both sub-groups soured on the Company post-vote is consistent with the stock price evidence about what the market was troubled by: the opinions voiced by FDA staffers and AdCom members on June 13, not the scientific findings or facts about Sanofi's provision of data to the FDA that were disclosed on June 11. Unlike the information released on June 11, which did not cause analysts to devalue the stock, the new information released on June 13 *did* cause analysts as a group to devalue the stock. See Exhibit 15.

100. Twenty-three analysts issued a report on Sanofi during the three-day post-AdCom period; eleven of them had also done so during the two-day interim period. Notably, 14 of the 23

did not downgrade the shares or the ADS during either period. That a majority left their rating unchanged suggests that even before June 11 many institutional investors did not expect U.S. sales of rimonabant to contribute much to Sanofi's bottom-line. See Exhibit 15.

101. In short, while some analysts who published during the 6/11-6/12 period became less optimistic about rimonabant's prospects, others did not, and none anticipated flat-out non-approval. The fact that analysts who were familiar with the FDA Brief did not regard its suicidality findings as making non-approval probable and that none changed their rating on the company is consistent with a showing that the information about suicidality was not material in and of itself, as I already established with the results of my June 11, 2007 event study.

102. Finally, if the market believed that the AdCom would necessarily vote against approval because of the revelation of the "causal link between rimonabant and suicidality," one would have expected the statistically significant price drop seen on June 13, 2007 to have come on June 11, 2007, when that information was publicly reported. But that did not happen.

**C. Even Before June 11, 2007, Sophisticated Market Participants—including Lead Plaintiff's Investment Manager—Recognized that Acomplia Was at Risk of a Negative AdCom Vote and Eventual Non-Approval**

103. Before the FDA Brief was posted on June 11, many analysts noted in their published reports the possibility that Acomplia might not be recommended by the AdCom or approved by the FDA. Of the ten analysts who issued a report commenting on rimonabant on June 11 or June 12, 2007, five mentioned the risk of non-approval or a less-than-unanimous Panel ratification in their last pre-June 11, 2007 report on the Company. See Exhibit 14.

104. Analysts were not the only sophisticated market participants who recognized before June 11, 2007 that Acomplia faced a non-trivial risk of not winning approval. Internal emails produced by Boston Partners, the investment manager to the Hawaii Annuity Trust for Operating Engineers, also reflect such an awareness:<sup>65</sup>

- October 31, 2006 11:55 a.m.

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<sup>65</sup> A00009-A000010, a Dec. 14, 2011 e-mail from Todd Knightly to William Butterly, incorporates all of the material cited below.

“F (32) Bad. ... On Oct 26 SNY filed the follow-up to its Acomplia approvable letter with the FDA, there was no clarity on whether the additional information will require a 2 or 6 months review period, but it seems less likely Acomplia will be approved in the US before yr end (mgmt previous guidance) Initial sales of Acomplia in Europe have been good.

Mo (73) Mixed. ... 07 eps may come down slightly do [sic] to the timing of FDA approval and launch of Acomplia in the US.”.

- February 13, 2007 9:26 a.m.<sup>66</sup>

“F (31) Ok. ... Acomplia, SNY’s biggest and most important pipeline product has been further delayed by an additional 3mth to allow the FDA to review additional trial results, this delay while a negative headline could prove beneficial if it allows for better labeling (to include type 2 diabetes). ...

Mo (30) Negative. ... Best chance for improving Mo will be the approval of Acomplia with a favorable label which includes a type 2 diabetes indication.”

- May 3, 2007 10:07 a.m.<sup>67</sup>

“V (33) Good. ... At 12.5x 08 eps SNY is trading at a discount to its historical ave and its peers. A discount is justified as SNY faces 3 important binary events in the near term.... the outcome of the recently completed Plavix trial, potential for a generic version of Lovenox and the FDA review panel for its largest and most important pipeline drug Acomplia.”

105. The above comments cannot be squared with Plaintiffs’ allegations that the market was misled by the challenged statements into believing that there were no major obstacles to rimonabant’s winning FDA approval. Even the investment manager of a named Plaintiff believed a non-approval discount to be baked into the stock.

#### **D. The Challenged Statements Did Not Alter Assessments of the Total Mix of Information**

106. In finding the February 24, 2006 and October 31, 2006 challenged statements to be actionable misstatements, the Court accepted as true Plaintiffs’ claim that the complaint sufficiently alleged that a reasonable investor might mistakenly conclude from the earlier statement that “the FDA had made no other requests and/or that the FDA approval process was

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<sup>66</sup> A00004, e-mail from Todd Knightly to Investment Personnel – Boston & Ann Carroll, Feb. 13, 2007.

<sup>67</sup> A00003, e-mail from Todd Knightly to Investment Personnel – Boston & Ann Carroll, May 3, 2007.

on track without any major concerns” and might conclude from the later statement that Sanofi “had not submitted new data on some issue that concerned the FDA.”<sup>68</sup> The Court ruled Plaintiffs had sufficiently alleged both statements to be material for purposes of ruling on the motion to dismiss.

107. As part of my own materiality assessment I looked to see whether Plaintiffs’ allegations were borne out by the facts. I did so by reviewing all Sanofi-specific English-language analyst reports published over the five days beginning with each statement that I was able to obtain from counsel, Thomson Investext, or Reuters.

108. To gauge analyst interpretations of the February 24 challenged statement, I reviewed reports published from that day through February 28, paying particular attention to what each analyst wrote regarding what the FDA requested of Sanofi in the approvable letter. I coded the reports based on five features of the analyst’s apparent “read” of that news: (1) no new data were requested; (2) no new clinical data were requested; (3) no new clinical trial was requested; (4) the FDA may have requested data other than from a new clinical trial; and (5) nothing said about an FDA request for new data or a new trial.

109. None of the 19 analysts stated that *no* new data were requested I conclude that none of the 19 analysts evidenced confusion about the February challenged statement.<sup>69</sup> My findings are detailed in **Exhibit 18**. The following excerpts evidence a clear awareness on the part of these analysts that Sanofi’s receipt of the approvable letter meant that the Company faced substantial hurdles (potentially including a data request) to win approval for rimonabant:

- “SNY’s post ‘approvable letter’ guidance for rimonabant (aka Acomplia) is for 2H-06 launch in the US and other select territories, consistent with our modeling. **We**

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<sup>68</sup> Order at 564-65, 568-69.

<sup>69</sup> The Dresdner Kleinwort and Morgan Stanley analysts stated that the FDA had requested no new clinical data but this does not signal confusion, particularly given that both recognized that no new clinical trials were called for. The Morgan Stanley analyst made clear in the report at issue that he heard exactly what the Company had said about what the approvable letter did not require; despite describing the message in one place as “no additional clinical data,” earlier in the report he wrote that “additional *clinical trial* data” were not required by the letter. Morgan Stanley, Sanofi-Aventis Positive Thesis Unchanged: Bumpy Road Ahead, Feb. 27, 2006 (emphasis added). For its part, Dresdner Kleinwort subsequently published a report that replaced the “clinical data” reference with the more exacting phrase “clinical trial”: “However, Acomplia now has an approvable letter and is not expected to require further clinical trials before approval,” and “At the beginning of 2006, we were cautious on the regulatory risk for Acomplia and predicted a delay at the FDA and possible issues on safety. While the delay at the FDA has occurred, the regulators seemingly have not raised any concerns over Acomplia’s safety profile and have not asked for any additional trials.” Dresdner Kleinwort, Appealing cash flow and upside from pipeline, July 4, 2006.

**believe FDA wants to see more safety data before issuing full approval, probably culled from one or more ongoing rimonabant trials. . . . Our best understanding of the current situation is that the FDA wants additional safety data on rimonabant before issuing a full approval. This safety data can probably be culled from one or more of the ongoing studies, and fits within management's guidance that for weight management no 'new' studies are being asked for by the agency. . . .** As we have written about previously, rimonabant is likely to launch with some form of 'risk management' program that the company and FDA find mutually acceptable that will essentially meter the uptake of the drug and will track more closely adverse events as they arise." Prudential, SNY: Rimonabant (aka Acomplia) Coming 2H'06 – Heavier Spending Assumptions Lowers Our '06 and '07 EPS, Feb. 26, 2006 (emphasis added).

- "We continue to believe that a number of issues that could substantially alter the commercial profile of the drug could remain outstanding. These include the CNS safety profile of the drug . . . . No new studies needed for Acomplia but what about data? There was little new information of the recent approvable letter for rimonabant in weight management and non-approval for smoking cessation except management did confirm that no new studies were needed for weight management. **However, it would not be drawn further on the contents of the letter nor confirm whether any new data is needed from existing studies nor whether outstanding issues related to safety or efficacy of the product as well as just labeling. As we have previously highlighted we believe that a number of issues could still remain outstanding at FDA . . . . FDA could still require additional analysis or data for clarification of either safety or efficacy issues . . . .** Whether any kind of risk-monitoring programme or restrictions on the label are required, given the potential for CNS (anxiety and depression) side effects, could still be a matter for discussion." Merrill Lynch, Overhangs remain, Feb. 27, 2006 (emphasis added).
- "With the delay of Acomplia's approval, the market has been focusing on 3 April as the next catalyst of volatility for Sanofi-Aventis . . . . With our continuing concerns on the prospects of Acomplia and potential for generic Lovenox this year, we maintain our Sell/ Medium Risk (3M) rating and our price target of €68 . . . . **Furthermore, the risk of failing to achieve FDA approval of Acomplia in 2006 has risen markedly after the failure of Sanofi-Aventis' first NDA submission.**" Citi, Plavix trial delayed until 12 June, Feb. 28, 2006 (emphasis added).
- "We believe the company itself will remain uncertain of the FDA's thoughts until they meet in March. **That the FDA did not request further trials might be positive, but not necessarily so. . . . The fact that the FDA has not requested additional clinical trials in obesity sounds positive but this is not clear,** given the FDA is aware of the large outcome studies underway or planned. We believe continued caution regarding Acomplia is warranted until the company has met with the FDA and is able to update the market, which might not be until the Q1'06 results on 5 May." UBS, Much Still to be Accomplished, Feb. 27, 2006 (emphasis added).

110. I used a similar protocol to assess interpretations of the October 31 challenged statement. In this case, I reviewed analyst reports from October 31 through November 4 and coded them with respect to six (not mutually exclusive) views that might have been expressed with regard to what Sanofi's submission to the FDA encompassed: (1) a complete response to the approvable letter; (2) no new data; (3) no new clinical data; (4) no data from a new clinical trial; (5) may have submitted new data or analysis but did not say that these may have been from a new clinical trial; or (6) nothing said about Sanofi's October 26 submission.

111. The reports of some analysts explicitly recognized that Sanofi must have submitted substantial additional data to the FDA, noting the length of time it had taken the Company to respond to the FDA. For example:

- “Disappointingly, we now believe that the US approval of Acomplia now appears unlikely before 2Q07 and we have delayed our assumed launch by 6-months to mid 07 in our model. Sanofi revealed that it had only submitted its complete response to the FDA's approvable letter on 26 October 2006. **Whilst the review time is uncertain with 2 or 6 months both possible, given the length of time taken to submit its response, we can only conclude that the response contains considerable amount of additional information which the FDA is likely to require 6 months to review . . .**” Merrill Lynch, New concerns for longer term growth, Nov. 1, 2006 (emphasis added).
- “Uncertainty on Acomplia Persists: SASY specified that Acomplia was re-submitted on October 26, 2006. **The time required for re-submission (>8 months) seems to indicate that the file included substantial additional data from the RIO studies, which should make a quick turn-around unlikely.** A class-2 re-submission could still require an advisory meeting. In the absence of hard data on weight-independent benefits on cardiovascular risk factors, we remain skeptical about Acomplia's commercial potential. In our opinion, four big issues that remain unresolved: 1) Why did it take so long for Sanofi to submit a complete response for Acomplia? . . . **It is still unclear why it took >8 months to fulfill the FDA requests outlined in the letter, especially since the company has repeatedly stated that data from new studies was not required. The time required for resubmission seems to indicate that the file included substantial additional data from the RIO studies, which could imply a concern regarding a safety signal or the analysis of the efficacy benefit observed, in our opinion.**” Bear Stearns, Downgrade from Peer Perform to Underperform, Nov. 1, 2006 (emphasis added).
- “Sanofi-Aventis revealed it had submitted a complete response to the FDA's approvable letter for Acomplia, although did not offer much clarity on the information provided to the FDA (other than that data had not been provided from

new clinical trials) . . . . We expect a 6-month review, with risk of further delay.”  
 UBS, Acomplia: A riddle wrapped in an enigma, shrouded in mystery, Nov. 1, 2006

112. Eighteen of the twenty analysts who published a report on Sanofi from October 31, 2006 through November 4, 2006 evidenced no confusion about the nature of the Company’s FDA submission.<sup>70</sup> A nineteenth analyst, from Lehman Brothers, is less readily classifiable in this regard because in one place he stated--correctly and with precision--that the FDA had not requested new clinical data, but later in the same report he wrote (perhaps sloppily) that the FDA had not requested new data.<sup>71</sup> Only one analyst, from Helvea, stated that Sanofi’s response “apparently did not include any additional data.” While the Helvea analyst failed to report Defendant Spek’s “in this respect” qualification, he expressed skepticism about rimonabant’s approval prospects (“there is no guarantee that the product will even make it to the market in the USA”), maintained only a Neutral rating on the stock, and noted that “management’s comments failed to shed much light on visibility for the drug.”<sup>72</sup> See Exhibits 19 and 20.

## VIII. CONCLUSION

113. Plaintiffs fail to distinguish between two radically different information sets in their attempt to claim June 13, 2007 – a day of significant ADS price drop – as the corrective disclosure date. In fact, their two actionable misstatements were cured neither by the FDA’s statistical findings (disclosed June 11 in any case) nor by an FDA scientist’s or the AdCom’s view that rimonabant’s risks outweighed its benefits as an obesity treatment (disclosed June 13). Rather, the actionable misstatements were cured by the much narrower June 11 news that the FDA had asked Sanofi to obtain certain suicidality-related data from Dr. Posner, and that Sanofi

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<sup>70</sup> The 18 include Prudential Equity Group and Societe Generale, who each wrote that Sanofi had submitted no new *clinical* data. This did not signal confusion, particularly given that both analysts correctly understood the FDA not to have requested data from new clinical trials. Thus, months earlier, the Prudential analyst had stated, “Our best understanding of the current situation is that the FDA wants additional safety data on rimonabant before issuing a full approval. This safety data can probably be culled from one or more of the ongoing studies, and fits within management’s guidance that for weight management no “new” studies are being asked for by the agency.” Prudential, SNY Rimonabant (aka Acomplia) Coming 2H’06 – Heavier Spending Assumptions Lowers Our ’06 and 07 EPS, Feb. 26, 2006. For its part, Societe Generale subsequently published a report replacing its “clinical data” reference with the more exacting “clinical trial,” stating: “The exact reasons for the FDA approvable letter as opposed to a straight approval have never been disclosed, but it appeared that the FDA did not require additional clinical trials as Sanofi-Aventis was able to provide its complete answer to the FDA on 26 October . . . .” Societe Generale, Hit or Miss, June 11, 2007 (report was published before the FDA Brief).

<sup>71</sup> Lehman Brothers, Poor sales and no clarity on Acomplia, Nov. 1, 2006.

<sup>72</sup> Helvea, Running into Deep Water, Oct. 31, 2006.

had done so and provided those data to the FDA. Moreover, even if the FDA's statistical findings were relevant, there was no statistically significant price reaction upon that information being disclosed.

114. Because the June 13 news is not relevant to this litigation, neither is Sanofi's ADS price drop that day and the next nor the ordinary shares' price drop on June 14. What does matter, critically, is the ADS's and ordinary shares' price behavior on June 11. While negative, this day's moves did not begin to approach statistical significance: a finding that undercuts Plaintiffs' claim of materiality, and therefore their entitlement to a presumption of reliance. Even if they had that presumption, the June 11 price findings would suffice to rebut it, by severing the link between the alleged omissions and price.

115. The failure of Sanofi's ADS or ordinary shares price to significantly fall on June 11 indicates that, even in combination, the news that the FDA had requested and received the Posner Codings from Sanofi *and* the news that the FDA found in those data a statistically significant association between rimonabant and suicidality was not material. A credible explanation for this lack of materiality is that the market had already priced roughly that much suicidality risk into the securities, and did not regard it as serious enough to preclude FDA approval.

116. My work is ongoing and my findings are as of the date of this report. I reserve the right to modify or expand the opinions expressed herein based on further consideration of existing information and/or additional documents and data provided to me, including but not limited to expert reports submitted by Plaintiffs.

117. In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

4/25/2012  
Date

Marcia Kramer Mayer  
Marcia Kramer Mayer, Ph.D.